STATE AND CONSUMERS AFFAIRS AGENCY DEPARTMENT OF CONSUMER AFFAIRS ARNOLD SCHWARZENEGGER, GOVERNOR

Licensing Committee Report

Members:

Susan Ravnan, PharmD, Chairperson James Burgard, Public Member Robert Graul, RPh Hank Hough, Public Member Stan Weisser, RPh

ITEM A: Report on the Meeting of June 23, 2008

1. Board Recognition of Schools of Pharmacy that have received precandidate status from the Accreditation Council for Pharmacy Education for Purposes of Issuing Intern Licenses

FOR ACTION:

Two Schools of Pharmacy have submitted requests to the board seeking board recognition for purposes of approving intern applications.

Current regulation, Title 16 CCR 1719, states that a "recognized school of pharmacy" means a school accredited, or granted candidate status by the Accreditation Council for Pharmacy Education (ACPE).

Sullivan University College of Pharmacy was granted precandidate status by the ACPE at their January 2008 meeting to admit their first class of students for enrollment in July 2008. Sullivan University is in the middle of their 2008/09 Review Period for advancement to Candidate accreditation status. COMMITTEE RECOMMENDATION: Board recognition of Sullivan University to allow students to obtain intern cards.

California Northstate College of Pharmacy (CNCP) was recently granted Pre-Candidate status by the ACPE this month to admit their first class of students in fall of 2008. The board staff received confirmation that CNCP has since received pre-candidate status.

ATTACHMENT 1 are the letters from Sullivan University College of Pharmacy and CNCP requesting recognition by the board.

Should the board choose to approve CNCP's request for board recognition a motion and vote will be required.

COMMITTEE RECOMMENDATION: None.

2. Recommendation to Update the Strategic Plan for the Licensing Committee 2008-09.

FOR INFORMATION:

In July 2006, the board finalized its strategic plan for 2006-2011. However, each year the board revises its plan to keep it current.

At the June 23, 2008 meeting, the Licensing Committee reviewed the strategic goals and objectives for the committee. No changes were discussed. The committee chair requested that board staff review how statistics are reported and ensure they conform to the performance standards identified.

COMMITTEE RECOMMENDATION: No changes to the committee goals and objectives.

ATTACHMENT 2 is the update of the committee's strategic plan.

3. Discussion of Licensure of Ambulatory Surgical Clinics by the Department of Public Health under Health and Safety Code Section 1204 That Are Owned by Physicians.

FOR INFORMATION:

The committee reviewed a letter from the California Ambulatory Surgery Association (CASA) requesting guidance from the board to rectify the regulatory consequences from *Capen v.Shewry (2007) Cal. App 4th 378* (Capen Decision) as it relates to the board's ability to issue a clinic permit to ambulatory surgical clinics.

Current law allows the board to issue a clinic license only to an entity also licensed by the Department of Public Health (DPH). The Capen Decision determined that DPH does not have jurisdiction over surgical clinics owned in part, or wholly by a physician. The ramifications of this decision is that DPH can no longer issue surgical clinics licenses to such entities, nor can such current licenses be renewed. The Capen Decision determined that regulation of such clinics falls under the prevue of the Medical Board. Without a license from DPH, the board is unable to issue a clinic license to allow such clinics to purchase drugs at wholesale as well as commingle medications. Without the

board issued license each prescriber must maintain a separate drug supply or the drug supply must be wholly owned by the professional director or some single prescriber.

CASA has pursued legislation that would have among other things, expanded the board's authority to issue a clinic license to those surgical clinics that were operating either under a DPH issued license, or those accredited by an approved agency or Medicare certified. The board has consistently had a support position on such legislation.

Until a legislative fix is provided, the board cannot issue a clinic license unless the entity is also licensed by DPH. The board will continue to renew existing clinic licenses that are no longer licensed by DPH.

AB 1574 contains provisions that would allow the board to issue a clinic license to entities licensed by DPH, as well as to those accredited as specified or Medicare certified. This legislation was discussed at the July 10, 2008, Legislation and Regulation Committee meeting. The Legislation and Regulation Committee is recommending a support position on this bill.

ATTACHMENT 3 is the letter from CASA.

4. Discussion Regarding Formation of an Industry Task Force to Evaluate Pharmacy Technician Qualifications.

FOR INFORMATION:

This year the California Society of Health-System Pharmacists (CSHP) sponsored legislation to increase the requirements for an individual to become licenses in California as a pharmacy technician. This bill was pulled due to concerns vetted by key pharmacy stakeholders, with the intent of pursuing legislation again in 2009.

CSHP is sponsoring stakeholder meetings to elicit recommendations and comments to refine the proposal for next year. The first stakeholder meeting was held on June 25, 2008. Board Member Stan Weisser was designated by President Schell to represent the board at these meetings and report back.

Discussion at both the committee meeting and the stakeholder meeting revealed that there is disagreement within industry about what and if there is a problem with the current existing pharmacy technician qualifications requirements as well as whether the draft legislative proposal correctly addresses the minimum qualifications. In addition, there appears to be disagreement about whether continuing education is appropriate for pharmacy technicians. **ATTACHMENT 4** contains the minutes from this stakeholder meeting.

The board also recently received a letter from Deborah Fernandez representing Valley Career College. This letter was to bring forth concerns that techician schools have in regards to AB 1947 as well as to offer potential changes concerning the California Society of Health-Systems Pharmacist Fact Sheet. This letter was also previously provided to Lynn Rolston of CPhA and Phillip Swanger of CHSP. **ATTACHMENT 5** is a copy of this letter.

5. Discussion to Amend 16 CCR Section 1728 to Increase the Number of Intern Hours That Can Be Earned Outside a Pharmacy.

FOR INFORMATION:

In 2006 the Licensing Committee considered a request to increase the number of intern hours that can be earned outside a pharmacy to qualify for licensure as a pharmacist.

Testimony provided at committee meetings by pharmacy students indicated that opportunities for pharmacists have expanded beyond the traditional areas of community and hospital practice settings. Many students would like the opportunity to gain experience in the pharmaceutical industry, managed care, regulatory affairs and association management, but are unable to do so because they cannot earn intern hours for this experience, which impedes their experience as students and future development as pharmacists.

At the December 2006 Licensing Committee meeting, the committee determined that it was premature to move forward with the students' proposal given that concurrent with this request, the Schools of Pharmacy in California where undertaking an initiative to establish core competency assessment of basic pharmacy intern skills.

The development of these core competencies was completed and is provided in **ATTACHMENT 6**.

At the June 23, 2008 meeting, the committee again discussed if the current intern requirement should be changed to allow additional hours to be earned outside a pharmacy. Comments included that the board could consider increasing the number of intern hours required by 400 and should consider other venues outside a licensed pharmacy where pharmacists perform services as acceptable for purposes of accruing intern hours. In addition, public comment suggested that the board should consider the mandated 300 hours of Introductory Pharmacy Practice Experience required by ACPE into any decision to change the requirements.

At the conclusion of this meeting, the committee decided to table any action at this time to alter the intern hour requirement.

6. Discussion of the Ability for Pharmacy Applicants to Pursue Board Licensure Concurrent with Department of Health Care Services (DHCS) Provider Recognition and Drug Enforcement Administration (DEA) Registration.

FOR INFORMATION:

Recently board staff was forwarded a request from a pharmacy applicant requesting that the board issue a pharmacy permit prior to the opening of the pharmacy to allow sufficient time for the owner to also obtain a DEA license and Medi-Cal provided number prior to beginning business. It was suggested that this matter be referred to the Licensing Committee for discussion and forward any recommendations to the July 2008 Board Meeting.

Board staff routinely work with pharmacy applicants who are also concurrently seeking licensure with the DEA as well as applying for a Medi-Cal provider number. Each agency initiates application processing without a board license number, which reduces the application review time, however some applicants appear to have a more difficult time navigating the requirements of each agency.

At the committee meeting, Christine Soto, licensing manager for the board, discussed with committee members the process for seeking concurrent license. Ms. Soto indicated that board staff routinely work with these other agencies and are available to assist applicants who experience delays in the process by contacting DHCS and the DEA as needed.

Board staff will update the *Frequently Asked Questions* portion of the Web site to incorporate information.

7. Status Report to the Committee on Continuing Education Audits

FOR INFORMATION:

Business and Professions Code section 4231 requires that the board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that he or she has completed 30 hours of approved continuing education during the two years preceding the application for renewal. This section also exempts this requirement for the first renewal of a pharmacist license. Effective in 2006, this section was amended to state that the board would not renew a license if proof of continuing education is not provided and instead requires the board to issue an inactive pharmacist license.

Since 2006, the board has used its enforcement discretion and has not fully implemented this requirement. Rather, the board is randomly conducting continuing

education audits on a monthly basis. Over the last year, these audits have revealed that approximately 12% of pharmacists audited provide false information on their renewal. As a result, the board completes an investigation substantiating the violation and a citation and fine is issued.

In addition to these audits, the board sends an average of 20–25 letters to pharmacists monthly who fail to certify the completion of the required continuing education. Because of delays in the programming changes necessary to fully implement the changes made to these requirements in 2006, the board has been handling much of this process manually. Board staff continues to advocate for the necessary programming changes required to the system. Absent the programming changes, board staff will begin to manually issue inactive pharmacist licenses to those individuals who fail to provide proof of their continuing education as required.

The committee discussed the current process by the board to notify pharmacists of insufficient continuing education and was advised that the board's primary goal is to obtain compliance with the requirement.

8. Quality Assurance Review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

FOR INFORMATION:

During the public comment portion of the April 2008 board meeting, the board heard comments from Jennifer DeLany regarding the board's Quality Assurance (QA) review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). Counsel advised the board that no action could be taken during that meeting and as such the board decided to place this discussion on a future agenda to allow for board discussion. This issue was brought before the Licensing Committee for discussion.

The board contracts with a psychometric firm who provides the board with expert guidance on the appropriate administration and scoring of the CPJE, including quality assurance assessments. The contractor determines the criteria that need to be met in evaluating the examination's performance before candidate scores are reported. Board staff recognizes the consequences that such reviews have on candidates and work closely with the contractor to release scores as soon as possible.

The CPJE is an essential function of the board's licensing program and decisions are not done arbitrarily or capriciously but with deliberate care and with consultation from experts in the field of exam review, testing and validation. The exam vendor determines when the board can release the exam scores. This is done to protect the integrity of the exam process. It is also done because the exam consultant is responsible for defending the validation of the exam in the case of a lawsuit.

The board is sympathetic to the anxiety and stress of the students. The board however, needs to ensure that, with public protection as the core, the exam is a valid assessment of whether or not each pharmacist applicant is minimally competent.

9. Competency Committee Report

FOR INFORMATION:

Both Competency Committee workgroups will be meeting in August 2008 at an annual meeting to discuss examination development. Each Competency Committee workgroup will also meet once in the fall.

The current competency committee chairperson has diligently and graciously served in this capacity since 2005. At the August 2008 meeting a new chairperson will assume these duties. The board greatly appreciates the time and commitment during a person's tenure as Competency Committee Chairperson.

Quality Assurance Assessment

The most recent quality assurance assessment ended June 2, 2008.

CPJE Statistics

The next CPJE statistical report should be available at the October board meeting.

10. Review and Discussion of "Standards and Guidelines for Healthcare Surge During Emergencies"

FOR DISCUSSION:

Earlier this year, the board received a copy of the "Standards and Guidelines for Healthcare Surge During Emergencies" manual prepared by the California Department of Public Health (CDPH). These documents are being released by CDPH to help healthcare providers, payers, local government and local communities better plan to sustain a functioning healthcare delivery system during a catastrophic emergency.

The manual included four volumes and is designed to provide guidance, operational tools and training curriculum for healthcare facilities, insurers, licensed healthcare professionals, local health departments, local communities and other interested parties. CPDH will issue manuals for community clinics, long-term care facilities and licensed

healthcare professionals. A copy of the manual can be obtained at the "Be Prepared California" Web site, www.bepreparedcalifornia.ca.gov.

The board continues to actively engage in disaster planning and response. Most recently the board took a support position on AB 2756 (Duvall) relating to the furnishing of dangerous drugs by a pharmacist during an emergency.

The recent wildfires and declared state of emergency again highlight the important role that pharmacists play in the delivery of healthcare.

The committee discussed prior challenges in geting prescriptions filled for patients during an emergency, such as the fires last October in Southern California. In addition, the committee discussed the challenges for residents in remote areas as well as the possible need for specifics and parameters for appropriate pharmacists' response in the case of a disaster.

The committee requested that the board continue to remind pharmacists on an ongoing bases of the guidelines established by the board and to use professional judgement in emergency situations.

ITEM B: Meeting Summary of the Licensing Committee Meeting of June 23, 2008.

FOR INFORMATION:

The Licensing Committee met on June 23, 2008. A copy of the meeting summary is provided in **ATTACHMENT 7.**

ITEM C: Licensing Statistics 2007-08

FOR INFORMATION:

ATTACHMENT 8 contains licensing statistics describing the Licensing Unit's processing activities for the third quarter of the fiscal year.

ITEM D: Third Quarterly Report on Committee Goals for 2007-08

ATTACHMENT 9 contains the fourth quarterly report on the committee's strategic goals for 2007/08.

Request from Sullivan University
College of Pharmacy and
California Northstate College of
Pharmacy

May 22, 2008

Virginia Herold Executive Officer California State Board of Pharmacy 1625 N. Market Blvd., Suite N219 Sacramento, CA 95834

Re: Recognition of Sullivan University College of Pharmacy

Dear Ms. Herold:

I would like to take this opportunity to petition the California State Board of Pharmacy to acknowledge our College of Pharmacy so that our students can be registered as interns in the State of California.

We are a new College of Pharmacy located in Louisville, Kentucky. We were recently granted Pre-Candidate status by the Accreditation Council for Pharmacy Education (ACPE) at their January 2008 meeting, allowing us to enroll our Inaugural Class to start July 7, 2008.

Our program is a unique three-year (36 month) professional program which allows students to complete the Doctor of Pharmacy degree following 2 years of pre-pharmacy requirements, save a year of tuition, and enter the workforce in a much shorter period of time. This program is comprised of the following pharmacy practice experiences:

Professional Year One

Initiation to the Practice of Pharmacy - Students will visit different settings and will come back to the classroom for discussions and debriefing. The delivery of patient-centered care will be examined from the different types of services in various settings. This will help the students to be introduced from the start to the variety of pharmacy practice.

Professional Year Two

Intermediate Pharmacy Practice Experience - Students will practice as a pharmacy extern five weeks in a community setting and five weeks in an institutional setting. They will learn the distribution of a drug from the prescription received to the safe administration of the drug to the correct patient. Students will also learn the operational aspects with all its related issues during the experiences.

Professional Year Three

Advanced Pharmacy Practice Experiences - The students will go through eight experiential education experiences of five weeks each. The experiences include a core of Adult Medicine, Ambulatory Care, Advanced Hospital Pharmacy, and Advanced Community Pharmacy and four electives. This will be the time for students to integrate and apply their knowledge to real patients' situations. It will also be an opportunity for the student to function as a team member of a health care team.

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Virginia Herold Executive Officer California State Board of Pharmacy May 22, 2008 Page Two

Listed below you will find the ACPE Detailed Accreditation History for the College, which was taken directly from their website (http://www.acpe-accredit.org/deans/schools.asp). As you can see, we are in the midst of the 2008-2009 Review Period for advancement to Candidate accreditation status. You may contact them directly at (312) 664-3575 if further information is required.

Detailed Accreditation History

Sullivan University College of Pharmacy

2100 Gardiner Lane Louisville, KY 40205 Hieu T Tran, PharmD

Dean

Tel: 502-413-8640 FAX: 502-413-8642

E-Mail: htran@sullivan.edu

Web Site: www.sullivan.edu/pharmacy

Review Period	Review Type	Board Action	Status
2008-2009	Comprehensive - Advancement to candidate		
2007-2008	Comprehensive - Precandidate status	Granted	Precandidate
2006-2007	Initial Application		

We thank you and the Board for your consideration of our petition. Should you need further information or have any questions, please do not hesitate to contact my office at 502-413-8641 or by email (<a href="https://https:

With Best Regards,

Hieu T. Tran, Pharm.D. Dean and Professor

Gen T. Tran, &

College of Pharmacy

Sullivan University

HTT/skw



March 6, 2008

Virginia Herold Executive Officer California Board of Pharmacy 1625 North Market Blvd, Suite N219 Sacramento, CA 95834

Dear Ms. Herold:

I am requesting that California Northstate College of Pharmacy (CNCP) be recognized by the California Board of Pharmacy as a new school of pharmacy in California.

CNCP received approval from the Bureau for Private Postsecondary and Vocational Education to operate in the state of California as a degree-granting institution on April 25, 2007. Since we are an autonomous college of pharmacy, we had to apply for both professional accreditation with the Accreditation Council for Pharmacy Education (ACPE) and regional accreditation with the Western Association of Schools and Colleges (WASC).

An application for pre-candidate status was submitted to ACPE on April 27, 2007, and we were invited to make a presentation to the ACPE Board on June 22, 2007. The Board granted an on-site evaluation, which was subsequently scheduled for October 30 – November 1, 2007. The ACPE Evaluation Team was impressed with our program, but expressed some concern that we were not yet in our building. We moved into our building on February 1, 2008, and requested a focused ACPE Evaluation visit this spring. The ACPE Board approved our request and a focused visit has been scheduled for April 24, 25, 2008. We anticipate receiving pre-candidate status in June, 2008. With the granting of pre-candidate status, CNCP will be permitted to enroll students and begin classes this fall. ACPE will evaluate our program for candidate status approximately one year after classes are begun. Full accreditation does not occur until we graduate our first class and the students have taken the NAPLEX exam.

An application for eligibility status was submitted to WASC on August 1, 2007, and we were granted eligibility status on November 15, 2007. Candidate status with WASC is expected to occur sometime in 2011 and full accreditation after we graduate the first class.

Ms. Virginia Herod March 6, 2008 Page 2

As you know, the revised ACPE Accreditation Standards call for 300 hours of introductory pharmacy practice experience (IPPE) over the first three years of the PharmD curriculum and 1440 hours of advanced pharmacy practice experience (APPE) in the fourth year. Our curriculum has been designed to provide 60 hours of IPPE each semester beginning with the second semester of the first year and running through the sixth semester of the third year to satisfy the new standard of 300 hours. During the first semester of the first year students will take an introductory to pharmacy course that will include the basic principles of dispensing, immunizations, and OSHA, HIPAA, and CPR training. Therefore, the first IPPE rotation will occur in January 2009, assuming ACPE pre-candidate status is granted.

More detailed information about our college can be obtained from our website at $\frac{\text{http://www.calnorthstate.org}}{\text{out}}$.

If I can personally provide any additional information about our college to the Board, please don't hesitate to contact me. My office telephone number is 916.631.8108. My email address is dhawkins@calnorthstate.org.

Thank you for giving our request to be recognized as a college of pharmacy by the California State Board of Pharmacy careful consideration.

Sincerely.

David Hawkins, PharmD

Varil un Sanhans

Professor and Dean

Licensing Committee Strategic Plan Update

LICENSING COMMITTEE

Goal 2:

Ensure the qualifications of licensees.

Outcome:

Qualified licensees

Objective 2.1	Issue licenses within three working days of a completed application by June 30, 2011.		
Measure:	Percentage of licenses issued within 3 work days		
Tasks:	 Review 100 percent of all applications within 7 work days of receipt. Process 100 percent of all deficiency documents within 5 work days of receipt. Make a licensing decision within 3 work days after all deficiencies are corrected. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements. Pharmacists Intern pharmacists Pharmacy technicians Pharmacies Non-resident pharmacies Wholesaler drug facilities Veterinary food animal drug retailers Designated Representatives (the non-pharmacists who may operate sites other than pharmacies) Out-of-state distributors Clinics Hypodermic needle and syringe distributors Withdraw applications of applicants not meeting board requirements or where the application has been abandoned. Deny applications to those who do not meet California standards. 		
Objective 2.2	Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2011.		
Measure: Tasks:	Percentage of cashiered application and renewal fees within 2 working days 1. Cashier application fees. 2. Cashier renewal fees		
Secret 5	Cashier renewal fees Secure online renewal of licenses		

Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2011.
Percentage of licensing records changes within 5 working days
 Make address and name changes. Process discontinuance of businesses forms and related components. Process changes in pharmacist-in-charge and designated representative-in-charge. Process off-site storage applications. Transfer of intern hours to other states
Implement at least 25 changes to improve licensing decisions by June 30, 2011.
Number of implemented changes
 Determine why 26 states do not allow the use of a CA license as the basis for transfer a pharmacist license to that state. Work with the University of California to evaluate the drug distribution system of its clinics and their appropriate licensure. Work with the Department of Corrections on the licensure of pharmacies in prisons. Work with local and state officials on emergency preparedness and planning for pandemic and disasters. Planning to include the storage and distribution of drugs to as sure patient access and safety. Evaluate the need to issue a provisional license to pharmacy technician trainees.
 Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians. Implement the Department of Consumer Affairs Applicant Tracking System to facilitate
 implementation of I-Licensing system, allowing online renewal of licenses by 2008. Participate with California's Schools of Pharmacy in reviewing basic level experiences required of intern pharmacists, in accordance with new ACPE standards. Implement new test administration requirements for the CPJE.
Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2011.
Number of public policy initiatives evaluated

Letter from the California Ambulatory Surgery Association



1148 Galaxy Drive, Yuba City, CA 95991 • Phone: (530) 790-7990 • Fax: (530) 790-7990

June 4, 2008

Virginia Herold Executive Officer California Board of Pharmacy 1625 North Market Blvd., N219 Sacramento, CA 95834

Dear Ms. Herold:

The California Ambulatory Surgery Association (CASA) seeks guidance from the California Board of Pharmacy (hereafter "board") to rectify the regulatory quagmire resulting from Capen v. Shewry (2007) 155.Cal.App 4th 378 as it pertains to an ambulatory surgery center (ASC) not having their "surgical clinic" license renewed by the California Department of Public Health (CDPH). Tantamount to our concern is the impact that decision and interpretation by the CDPH will have on those facilities that have obtained a limited pharmacy license from the board. Furthermore, CASA seeks guidance from the board as to the appropriate methods for an ASC to handle these drugs in lieu of being able to obtain a limited pharmacy license from the board.

As you know, CASA has been working tirelessly over the last three years pursuing legislation that would establish a consistent, concise and comprehensive set of transparent state-specific licensure requirements for the ASC industry. In addition, this effort has also included a pathway for all types of ASCs to appropriately obtain a limited pharmacy license from the board in order to allow an accredited outpatient setting or Medicare certified ambulatory surgical center to purchase a limited supply of drugs at wholesale and require these drugs to be stored safely by that facility. CASA would like to formally thank the board for its ongoing support of these efforts.

Existing law defines an Ambulatory Surgery Center (ASC) as a surgical clinic that is essentially not part of a hospital and is eligible for state licensure. AB 595 (Chapter 1276) of 1994 required that certain outpatient settings (including ASCs) to either be licensed by the state, Medicare certified or accredited by an agency approved by the Division of Licensing within the Medical Board of California (hereafter "MBC"). The intent was to "ensure that health care services are safely and effectively performed in these settings."

Even though existing law provides adequate oversight for ASCs utilizing certain levels of anesthesia, the board will not issue a pharmacy permit (i.e. limited pharmacy license) to an ASC until it can document state licensure. However, *Capen v. Shewry (2007) 155.Cal.App.4th 378* has prohibited the CDPH from issuing state licenses to almost all ASCs. As a result, accreditation and Medicare certification are the only other regulatory options for most ASCs. Unfortunately, individual staff physicians and surgeons are therefore required to acquire and maintain on-hand a myriad of medications to dispense at the point of care as opposed to those medications simply being readily centralized and available by the ASC.

We appreciate your prompt attention to this matter. For any further assistance in this matter, please contact CASA Legislative Advocate Bryce W.A. Docherty at (916) 446-4343 or bryce@thedochertygroup.com.

Sincerely,

Debbie Mack President

cc:

Jennifer Kent, Deputy Legislative Affairs Secretary, Office of Governor Arnold Schwarzenegger Anne Sodergren, Assistant Executive Officer, California Board of Pharmacy Monica Wagoner, Deputy Legislative and Government Affairs Director, California Department of Public Health

¹ Health & Safety Code §1204(b)(1)

² Business & Professions Code §§2215 et seq., Health & Safety Code §§1248 et seq.

Minutes from June 25, 2008
Stakeholder Meeting, sponsored by
the California Society of HealthSystems Pharmacists

PHARMACY TECHNICIAN STANDARDS STAKEHOLDER MEETING MINUTES

STATE CAPITOL, ROOM 125 SACRAMENTO, CA

WEDNESDAY, JUNE 25, 2008

PRESENT	REPRESENTING
Asm. Bill Emmerson	CA State Assembly
Jennifer Heutter	Asm. Bill Emmerson
Dawn Benton	CA Society of Health-System Pharmacists
Bryce Docherty	CA Society of Health-System Pharmacists
Philip Swanger	CA Society of Health-System Pharmacists
Anne Sodergren	CA Board of Pharmacy
Becky Ravnan	ExCPT
Camy Porru	Kaiser
Debbie Hernandez	Valley Career College
Debra Veal	CVS
Eric Douglas	Walgreens
Gail Blanchard-Saiger	CA Hospital Association
Heidi Barsuglia	CA Retailers Association
John Cronin	CA Pharmacists Association
Libby Sanchez	UFCW
Lisa Rystad	National Career Education
Lynn Rolston	CA Pharmacists Association
Mary Staples	NACDS
Mike Podgurski	Rite Aid
Peter Kellison	Walgreens
Richard Mazzoni	CVS Caremark
Stan Weisser	CA Board of Pharmacy
Trent Smith	Rite Aid

CALL TO ORDER

Assemblyman Bill Emmerson called the meeting to order at 3:01 PM.

PHARMACY TECHNICIAN STANDARDS STAKEHOLDER MEETING MINUTES

SUBJECT	DISCUSSION	SUGGESTIONS
Welcome & Introductions	Assemblyman Bill Emmerson, author of AB 1947, welcomed stakeholders. Stakeholders introduced themselves.	Mandatory PTCB or psychometrically sound testing.
Background on AB 1947	 Bryce Docherty provided historical background of past pharmacy technician related medication error incidents in Florida, Ohio, and California. Detailed how recommendations were formulated from CSHP House of Delegates, focusing on training, continuing education, and passing a standardized test. Informed stakeholders that AB 1947 was pulled in 2008 in good faith so that stakeholders could vet issues and Asm. Emmerson could run a consensus bill in 2009. 	 Mandatory CE. Minimum age requirement of 18. Mandatory Board of Pharmacy Approved Employer Educational Training Program. Minimum number of
Round Table Discussion of Issues	 Peter Kellison, Walgreens, mentioned that he would like the house of pharmacy to come up with a joint proposal before other stakeholders are asked to provide feedback. Camy Porru, Kaiser, relayed that Kaiser would like to keep the burden of ensuring competent pharmacy technicians on the employer. Mary Staples, NACDS, mentioned that they currently like the 4 options for pharmacy technician licensure, and agrees that the house of pharmacy needs to come together first. Lynn Rolston, CPhA, commented on how crucial it is to have a well trained pharmacy technician. She asked that it is unclear what a well trained pharmacy technician looks like? Different employers will have different opinions on what illustrates a well trained pharmacy technician. In terms for CPhA, they need flexibility in the types of training programs available. PTCB and the other requirements establish a baseline to which training must be added. Suggested that perhaps it is necessary to have two types of pharmacy technicians. Libby Sanchez, UFCW, and Richard Mazzoni, CVS Caremark, were interested in how big of a problem is the current pool of competent pharmacy technicians. Libby Sanchez, UFCW, asked how available online CE is for pharmacy technicians and was curious how grandfathering will be addressed. Bryce Docherty, CSHP, mentioned that in the current language of the bill, pharmacy technicians will have an outward deadline to pass the PTCE, which is a one-time exam for \$129. 	educational hours (i.e. 250) regardless of educational pathway. Minimum hours of work under the supervision of a pharmacist.

PHARMACY TECHNICIAN STANDARDS STAKEHOLDER MEETING MINUTES

SUBJECT	DISCUSSION SUGGESTIONS
Round Table Discussion of Issues (continued)	 Philip Swanger, CSHP, mentioned that PTCB offers over 60 units of free pharmacy technician education online. Debbie Hernandez, Valley Career College, pointed out that their students receive 550 hours of training. Concerns were raised in regards to the PTCB only holding it's test 4 times a year and have test locations that may be hard to reach. Becky Ravnan, ExCPT, mentioned that ExCPT exam has been psychometrically validated, is less expensive to take than the PTCE, and is offered more often and in more locations. ExCPT will be approaching the CA Board of Pharmacy to support their exam. This change must be done in statute. Dawn Benton, CSHP, pointed out that the current language would allow for pharmacy technicians to take a psychometrically sound exam approved by the CA Board of Pharmacy. Suggested that onus to track pharmacy technician requirements be placed on employers and that all pharmacy technicians must go through an employee training program.

ADJOURNMENT

There being no further business or discussion, the meeting was adjourned at 4:00 PM.

Letter from Valley Career College regarding the Task Force to Evaluate Pharmacy Technician Qualifications

VALLEY CAREER COLLEGE

878 Jackman Street El Cajon, CA 92020

BOARD OF PHARMACY

2000 JUN 20 PM 4: 36

Phone (619) 593-5111 Fax (619) 593-5114

June 17, 2008

Virginia Harold Executive Officer California State Board of Pharmacy 1625 N. Market Blvd, Suite N 219 Sacramento, CA 95834

Re:

June 16, 2008 Memorandum To Board of Pharmacy Licensing Committee -Subject Task Force To Evaluate Pharmacy Technician Qualifications CSHP Fact Sheet

Dear Ms. Harold

MY INTRODUCTION

I am the Pharmacy Program Specialist/Director of Career Services for Valley Career College in San Diego county. Due to time and work constraints, I cannot attend to be heard in person, but let me assure you I wish I could, as this subject is of high concern to me.

I would like to bring forth the following concerns that tech schools would have in regards to AB 1947 (Emmerson) as the Pharmacy Program Specialist/Director of Career Services for Valley Career College, and offer potential changes concerning the California Society of Health System Pharmacists Fact Sheet that I was provided via e-mail on June 11, 2008. In response to this June 11th e-mail, I have previously sent this letter to Lynn Rolston of CPhA as well as Phillip Swanger of CSHP

FACT SHEET SUMMARY

The summary provided reads as follows "Existing law authorizes the California Board of Pharmacy to issue a pharmacy technician license to an individual that has obtained a high school graduate or possesses a general educational development certificate equivalent. In addition, the individual must also meet any one of the following requirements to become licensed:

- 1. Has obtained an associates degree in pharmacy technology.
- 2. Has completed a course of training specified by the board.
- 3. Is certified by the Pharmacy Technician Certification Board.

Furthermore, while pharmacists are required to complete 30 hours of continuing education every 2 years to renew their pharmacy license, pharmacy technicians are not required to take any continuing education before renewing their pharmacy technician license. This bill would simply

require that all individuals seeking pharmacy technician licensure pass a psychometrically validated pharmacy technician certification exam prior to licensure, and that prior to renewing their license, pharmacy technicians successfully complete 20 hours of pharmacy technician approved continuing education."

MY PROPOSED SUMMARY CONCERNING THE FACT SHEET

- 1. In the first paragraph line 2-3 should correctly read "that has obtained a high school diploma"
- 2. Based on current state laws, and those provided by our national accreditation organization governing how vocational schools operate as to the placement of their graduates would make the addition of mandatory PTCB testing very unkind to vocational technician schools.
 - a. Department of Consumer Affairs (formerly Bureau for Private Postsecondary Vocational Education) law states that a school must place 70% of its graduates directly in their field of training within 180 days of training completion.
 - b. Accrediting Council For Continuing Education and Training (ACCET) law states that a school must also place 70% of its graduates directly in their field of training within the year of graduation. For example a graduate of October December would not have time to take, get the results of PTCB, retake if necessary, and obtain employment before the reporting time (March 31) would conclude. At this point the graduate's skills would become rusty thus decrease placement chances. If the certification exam was taken and not passed it would be almost impossible to place this student due to the exam failure and lack of confidence and selfesteem to try again.

If there is to be a computer based certification exam requirement we ask that it must be offered at more sites and results should be available more quickly. PTCB needs to make it possible for the computer based exam to be given at any school. PTCB could require each site/school to have the exam proctor that is approved by PTCB. For example, Valley Career College currently uses CPAT (Career Programs Assessment Test) to ensure that our students can effectively master the materials they will encounter in their programs. Those students that are accepted for programs other than pharmacy, who do not have a high school diploma or GED sit this exam, which is proctored by an non Valley Career College employee, who must meet the CPAT proctor requirements, and be in current good standing on their approved proctor list.

Experience shows that to require a recent graduate to go to a distant test site would create too much test anxiety. Other careers such as emergency medical technician and certified nurse assistant routinely bring in proctors to complete the student exams on site. Also, if a graduate needs to wait several months for exam dates or test results, during which time they cannot work as a technician immediately, this creates a large problem for vocational schools based on the state and national placement standards.

I would agree to enacting a requirement that all licensed technicians be required to obtain continuing education at 20 hours per licensing cycle. In 2004 at Outlook, APT brought this idea as new business before the House of Delegates Reference Committee and it is my recollection that CPhA voted in the House of Delegates to adopt this policy. I was very new to CPhA at the time and did not understand that this would not completely change the law.

If I could really gain, what would be an amenable solution to the immediate certification clause, it would be to grant a technician license for 1 year and change the law so that 20 hours of continuing education and that passing the PTCB or other approved certification exam recognized by the State Board of Pharmacy result in renewal of the pharmacy technician license.

FACT SHEET BACKGROUND

The fact sheet background reads "Pharmacy Technicians have a broad range of training and responsibilities in the healthcare arena. Under the direct supervision and control of a pharmacist, a pharmacy technician can perform packaging, manipulative, repetitive, or other nondiscretionary tasks related to the processing of a prescription in a pharmacy. Additonal nondiscretionary tasks include: (a) removing the drug or drugs from stock; (b) counting, pouring or mixing pharmaceuticals, (c) placing the product into a container into a container; (d) affixing the label or labels to the container; and (c) packaging and repackaging. Pharmacy Technicians may also, under certain conditions, check the work of other technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to an acute care general hospital whose orders have previously been reviewed and approved by a licensed pharmacist. There are over 50,000 practicing technicians in California that must renew their license every 2 years."

MY PROPOSED BACKGROUND CONCERNING THE FACT SHEET

1. Footnote 4 CA Code of Reg, Division 17, Title 16, Article 11 \$ 1793.8(a) Since this statute states in (a)(1) that it shall only apply to acute care inpatient hospital pharmacy settings with a clinical pharmacy program, and that this technician would still need further specialized and advanced training as prescribed in the policies and procedures of the facility, I feel strongly that this has little to do with a technician that is a fresh graduate from a technician school. Most all hospital employers routinely require at least one year of experience in a retail or outpatient setting before applying as an inpatient pharmacy technician. Therefore, in conjunction with the wording of this statute, I just do not see how the education and passing of the PTCB for a new pharmacy technician graduate would make any significant change for the better to this already stringent procedure. Would there then be consideration statewide that if you pass PTCB and graduate from a technician school, that this would automatically waive the one year experience requirement? I don't see this easy accepted by San Diego pharmacists.

The statement that reads "There are over 50,000 practicing pharmacy technicians in California that must renew their license every 2 years." Seems irrelevant.

FACT SHEET PROBLEM

The fact sheet background reads "As there is no standard for pharmacy technician training and licensure beyond being a high school graduate or having an equivalent degree, pharmacy technicians have a broad range of experience, education, and training."

MY PROPOSED PROBLEM CONCERNING THE FACT SHEET

This is what I consider to be the true problem at hand.

It is my belief that the board should increase the number of hours required for pharmacy education from 240 clock hours to a total of 720 hours as this would better meet the needs of today's pharmacy, and be in line with what vocational schools traditionally believe is the minimum amount of time that it takes to give new technicians a solid base to learn from. Currently the state board does not even have the externship time reportable on the transcript when filing for initial licensure.

Since I wrote a comprehensive programs for my school that routinely meets my current placement laws cited earlier, it is my belief that a standardization of curriculum taught statewide would be more in line with correcting this problem. There are also several pharmacy chains that sometimes offer their own internal training programs as well.

FACT SHEET SOLUTION

The fact sheet solution reads "AB 1947 (Emmerson) would increase the requirements for an individual to become licensed in California by requiring all individuals seeking pharmacy technician licensure to pass training, a psychometrically validated pharmacy technician certification exam. In addition, this bill would also require that a licensed pharmacy technician take 20 hours of pharmacy technician approved continuing education every 2 years prior to renewing their license."

MY PROPOSED SOLUTION CONCERNING THE FACT SHEET

Since we are currently not having a shortage of qualified technicians with experience, it is my belief that the following is a more amenable solution to keep the technician schools alive:

- 1. Collect and adopt an approved pharmacy technician training program that fully encompasses training for the retail, compounding, closed door setting, customer service call center, mail order, and introduction to hospital procedures.
- 2. Require 20 hours of continuing education for all technicians.
- 3. Change the policy of required training hours from 240 to at least 720 hours.

4. If PTCB must be accomplished, grant a one year license and give new technicians time to effectively learn the required material. To date even on PTCB's website they do not guarantee any review source for study material. And their review books have stated that you should work with a pharmacist for a minimum of 6 months before taking this exam.

FACT SHEET CONCLUSION

The fact sheet conclusion reads "AB 1947 (Emmerson) ensures that pharmacy technicians licensed by the California State Board of Pharmacy meet a universal standard by not only having a high school or equivalent degree but also pass training, a psychometrically sound pharmacy technician exam, and complete approved continuing education to better protect Californian consumers."

MY PROPOSED CONCLUSION CONCERNING THE FACT SHEET

It is my belief that AB 1947 would do great harm to the technician schools and would not accomplish a greater purpose at this time.

It is my suggestion that both CPhA and CSHP form a collective task force comprised of pharmacy technicians, I would accept one educational pharmacist as a member, and to seek more input from school owners, directors, and placement personnel before this new task force makes any further decisions regarding the licensing of technicians and this issue. I was a member of the last task force. We had one meeting and there was no unanimous agreement on anything. We simply opened dialogue that remained unfinished.

For further questions I can be reached at (619) 593-5115.

11.

Deborah J. Fernandez

Sincerely,

Introductory Pharmacy Practice Experience – Core Competencies

Competencies for Introductory Pharmacy Practice Experiences (IPPEs)

Through Introductory Pharmacy Practice Experiences (IPPEs), pharmacy students are expected to master foundational competencies in three domains: Communication and Professional Behavior, The Practice of Pharmacy, and Public Health. These competencies address the basic skills that prepare the student for the Advanced Pharmacy Practice Experiences (APPEs) offered through the pharmacy curriculum. As such, they represent an intermediate point in the professional development of a pharmacist. They are applicable across a spectrum of practice and other experiential settings and are expected to build in complexity over time.

The Purpose of the Introductory Pharmacy Practice Experiences (IPPEs) is to:

- Develop the basic knowledge, skills, and attitudes for pharmacy practice
- Instill professionalism

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• Expose students to the roles of the pharmacist and pharmacy practice settings

Communication and Professional Behavior

Upon completion of the IPPEs, the pharmacy intern should be able to:

A. Communicate effectively.

- 1. Communicate accurate and appropriate medical and drug information to a pharmacist, preceptor or other health care professional in a clear and concise manner
- 2. Determine the appropriate means of communication for the situation.
- 3. Actively listen to patients, peers, and other health care professionals.
- 4. Use proper grammar, spelling, and pronunciation in communications.
- 5. Explain medication information to patients in understandable terms.
- 6. Adjust communication based on contextual or cultural factors, including health literacy, language barriers, and cognitive impairment.
- 7. Routinely verify patient or recipient understanding of communicated information.
- 8. Demonstrate effective public-speaking skills and the appropriate use of audiovisual media when communicating with groups of patients, peers, and other health care professionals.
- 9. Develop effective written materials for patients, peers, and other health care professionals.

B. Interact with patients & the health care team.

- 1. Articulate the pharmacist's role as a member of the health care team.
- 2. Establish professional rapport with patients and healthcare professionals.
- 3. Demonstrate sensitivity to and respect for each individual's needs, values, and beliefs, including cultural factors, religious beliefs, language barriers, and cognitive abilities.
- 4. Demonstrate empathy and caring in interactions with others.
- 5. Maintain patient confidentiality and respect patients' privacy.
- 6. Demonstrate ability to resolve conflict in the pharmacy practice setting.

C. Behave in a professional and ethical manner.

- 1. Dress professionally and appropriately for the practice setting.
- 2. Arrive punctually and remain until all responsibilities are completed.
- 3. Use time effectively and efficiently.
- 3. Distinguish professional interests from personal interests and respond appropriately.
- 4. Demonstrate awareness of personal competence and limitations and seek guidance or assistance from preceptors when appropriate.
- 5. Accept responsibility for one's actions.
- 6. Respond appropriately to feedback from preceptors, patients, peers, and other health care professionals.
- 7. Show initiative in interactions with patients, peers, and other health care professionals.
- 8. Demonstrate passion and enthusiasm for the profession.
- 9. Be aware of and work appropriately within the culture of the assigned practice setting.
- 10. Demonstrate awareness of site or institutional policies and procedures.
- 11. Prioritize workload appropriately.
- 12. Identify issues involving ethical dilemmas.
- 13. Weigh and balance different options for responding to ethical dilemmas.
- 14. Propose steps to resolve ethical dilemmas.
- 15. Adhere to all state and federal laws and regulations as a pharmacy intern in the practice setting.

II. The Practice of Pharmacy

Upon completion of the IPPEs, the pharmacy intern should be able to:

A. Organize and Evaluate Information.

- 1. Assess prescription or medication orders for completeness, authenticity, and legality
- 2. Verify that dose, frequency, formulation, and route of administration on prescription or medication orders are correct.
- 3. Obtain any pertinent information from the patient, medical record, or prescriber as needed for processing prescription or medication orders (e.g., allergies, adverse reactions, diagnosis or desired therapeutic outcome, medical history).
- 4. Review the patient profile or medical record for any allergies or sensitivities.
- 5. Determine the presence of any potential medication-related problems.
- 6. Determine if it is legal and appropriate to refill a prescription, contacting the prescriber for authorization if necessary.

B. Prepare and dispense medications.

- 1. Accurately enter patient information into the patient's pharmacy profile or medication record.
- 2. Select the correct drug product, manufacturer, dose, and dosage form and prepare it for dispensing.
- 3. Assure that the medication label is correct and conforms to all state and federal regulations.

- 4. Assure that the label conveys directions in a manner that is understandable to the patient and that appropriate auxiliary labels are attached.
- 5. Select an appropriate container for storage or use of medications with special requirements (e.g., child-resistant containers, compliance devices).
- 6. Accurately perform and document the necessary calculations to correctly prepare the medication.
- 7. Perform the required technical and basic compounding steps to produce a pharmaceutically elegant product.
- 8. Demonstrate aseptic technique during the preparation of parenteral medications.
- 9. Document the preparation of any medication that has been compounded, repackaged, or relabeled.
- 10. Adjudicate third-party insurance claims using established billing systems
- 11. Determine the appropriate storage of medications before and after dispensing.
- 12. Comply with all legal requirements and professional scope of practice.

C. Provide patient counseling.

- 1. Communicate pertinent information to the patient to encourage proper use and storage of medications.
- 2. Discuss any precautions or relevant warnings about medications or other therapeutic interventions.
- 3. Assure that the patient comprehends the information provided, including what to do in the event that a medication-related problem occurs.
- 4. Assess and reinforce the patent's adherence to the prescribed therapeutic regimen.

D. Maintain accurate records.

- 1. Document the preparation and dispensing of medications.
- 2. Maintain manual or computerized files for prescription records that conform to state and federal laws and regulations.
- 3. Adhere to state and federal laws and regulations related to inventory control (e.g., controlled substances, investigational drugs).

E. Assist patients seeking self care.

- 1. Assess a patient's self-identified problem (e.g., common cold, fever, pain, gastrointestinal problems) to determine if the problem is appropriate for self care or requires referral.
- 2. Discuss options for treatment and recommend appropriate non-prescription product(s) if indicated.
- 3. Counsel the patient about the proper use of self care products
- 4. Instruct a patient about the proper use of a diagnostic agent or device, including directions for obtaining accurate results and how to interpret the results.
- 5. Teach a patient the proper and safe use of commonly used health products (e.g., condoms, thermometers, blood pressure monitoring devices, blood glucose meters, metered-dose devices, ear syringes, adherence devices).

F. Contribute to the optimal use of medications

- 1. Articulate the pharmacist's role in medication use oversight (e.g., formulary management, practice guidelines).
- 2. Participate in established medication safety and quality improvement activities (e.g., adverse drug reaction reporting, medication reconciliation).

- 3. Access, select, utilize, and cite appropriate references for health information and patient education materials.
- 4. Demonstrate basic proficiency with the technology used at assigned IPPE sites.

III. Public Health

Upon completion of the IPPEs, the pharmacy intern should be able to:

- A. Participate in health education programs and community-based health interventions.
 - 1. Raise public awareness about the role of a pharmacist as a public health educator.
 - 2. Participate in activities that promote health and wellness and the use of preventive care measures.
 - 3. Articulate the concept of advocacy what it means both professionally and personally.
- B. Demonstrate public health-related practice skills.
 - 1. Administer subcutaneous, intramuscular or intradermal injections, including immunizations.
 - 2. Screen for common medical conditions and make appropriate referrals.
 - 3. Conduct smoking-cessation interventions when appropriate.

Developed by the California Pharmacy IPPE-OSCE Initiative work group representing California's seven schools and colleges of pharmacy, the California State Board of Pharmacy, and the practice sector.

Co-Chairs: Barbara Sauer, PharmD (UCSF), Kathy Besinque, PharmD (USC), Eric Boyce, PharmD (UOP)

Participants: Sarang Aranke, PharmD (Target), Melvin Baron, PharmD (USC), Elizabeth Boyd, PhD (UCSF), Sian Carr-Lopez, PharmD (UOP), James Colbert, PharmD (UCSD), Robin Corelli, PharmD (UCSF), Larry Drechsler, PharmD (Target), Jeff Goad, PharmD (USC), William Gong, PharmD (USC), Steven Gray, PharmD, JD (Kaiser), Virginia Herold (California Board of Pharmacy), Donald Hsu, PharmD (Western), Gamal Hussein, PharmD (Loma Linda), LaDonna Jones, PharmD (Loma Linda), Linh Lee, PharmD (Ralphs), Paul Lofholm, PharmD (CPhA), Susan Ravnan, PharmD (California Board of Pharmacy), Debra Sasaki-Hill, PharmD (Touro), Sam Shimomura, PharmD (Western), Anne Sodergren (California Board of Pharmacy), Rick Sylvies, PharmD (Western), Reza Taheri, PharmD (Loma Linda), Dianne Tobias, PharmD (Medpin), David Williams (Safeway), Sharon Youmans, PharmD, MPH (UCSF), Keith Yoshizuka, PharmD, MBA, JD (Touro)

May 2007

Meeting Summary of the June 23, 2008 Licensing Committee Meeting

California State Board of Pharmacy

1625 N. Market Blvd, Suite N219, Sacramento, CA 95834 Phone (916) 574-7900 Fax (916) 574-8618 www.pharmacy.ca.gov STATE AND CONSUMERS AFFAIRS AGENCY DEPARTMENT OF CONSUMER AFFAIRS ARNOLD SCHWARZENEGGER, GOVERNOR

STATE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS LICENSING COMMITTEE MINUTES

DATE:

June 23, 2008

LOCATION:

Department of Consumer Affairs

El Dorado Meeting Room

1625 North Market Boulevard, Suite N220

Sacramento, CA 95834

BOARD MEMBERS

PRESENT:

Susan L. Ravnan, PharmD, Chairperson

Robert Graul, RPh

Stanley C. Weisser, RPh

Henry "Hank" Hough, Public Member James Burgard, Public Member

STAFF PRESENT:

Virginia Herold, Executive Officer

Anne Sodergren, Assistant Executive Officer

Chairperson Ravnan called the meeting to order at 1:00 p.m.

Request for Board Recognition of Schools of Pharmacy (16 CCR §1719) for School with Accreditation Council for Pharmacy Education (ACPE) Precandidate Status

- Sullivan University, College of Pharmacy
- California Northstate College of Pharmacy

Virginia Herold noted that the board can only act on one of the two requests.

Chairperson Ravnan indicated that the Sullivan University College of Pharmacy was granted pre-candidate status by ACPE in January of 2008, to admit their first class in July of this year. They are in the middle of their 2008-2009 review period for advancement to candidate status. The letter from Sullivan University requesting board recognition was provided in the committee packet prior to the meeting.

Chairperson Ravnan advised the committee, that California Northstate College of Pharmacy also submitted a request for board recognition, however, unlike Sullivan

University, California Northstate College still under consideration for pre-candidate status. At the time of the committee meeting, the board was not yet advised if this status was granted. As such, no committee action could be taken on California Northstate's request, rather it was a discussion item only.

Executive Officer Herold detailed the reason for these letter requesting board recognition. Specifically a school must be accredited by the American Council on Pharmaceutical Education (ACPE) under California Law in order for the student to receive an intern card. If the school is not accredited, ACPE approved candidate status will be accepted. In the case of these two schools, neither has received candidate status at this point. Pre-candidate status is granted to allow a college to enroll their first class.

The board has contacted ACPE and has confirmed that Sullivan University is moving appropriately in the process towards candidate status. Board staff is recommending that the committee recommend to the full board approval of the Sullivan University's request, thereby granting the ability of its student to apply for an obtain intern cards.

Bob Graul asked if this is typical to do for out-of-state schools. Ms. Herold answered that it is, because many of their students may be California residents, thus allows them to pursue internships when they return.

Lorie Rice (UCSF, School of Pharmacy) asked why the approval is a recommendation only. Ms. Herold explained that it must be approved by the full board, so the committee is deciding today on whether to recommend to the Board to act on this.

Ms. Rice asked if Sullivan has a campus in California. Ms. Herold indicated that they do not, but many students may be California residents.

Ms. Herold noted that, in the case of Northstate, they are still working with ACPE to obtain pre-candidate status. That decision should be made sometime this week, but the board does not have that information.

Ms. Rice asked if Northstate will have a campus in California and when the first students will be enrolled.

Ms. Herold responded that the campus will be in California and that students will be enrolled for the Fall of 2008 semester. Consideration for intern cards can be approved by the board at the next board meeting if appropriate.

MOTION: To recommend board recognition of Sullivan University to allow students the ability to obtain intern cards so that they may earn intern hours towards licensure.

M/S: BG/SW

SUPPORT: 4 OPPOSE: 0

<u>Discussion of Licensure of Ambulatory Surgical Clinics by the Department of</u> Public Health under Health and Safety Code §1204 that are Owned by Physicians

Chairperson Ravnan referred to an attachment provided in the committee packet, a letter from the California Ambulatory Surgery Association (CASA) requesting guidance from the board to rectify regulatory consequences from *Capen v. Shewry (2007) Cal.* App 4th 378 (Capen Decision) as it relates to the board's ability to issue clinic permits to ambulatory surgical clinics.

Chairperson Ravnan explained that current law allows the board to issue a clinic license only to an entity also licensed by the Department of Public Health (DPH). The Capen Decision determined that DPH does not have jurisdiction over surgical clinics owned in part, or wholly by a physician. The ramifications of this decision is that DPH can no longer issue surgical clinic licenses to such entities, nor can such current licenses be renewed. The Capen Decision determined that regulation of such clinics falls under the purview of the Medical Board. Without a license from DPH, the board is unable to issue a clinic license to allow such clinics to purchase drugs at wholesale as well as commingle medications. Without the board issued license each prescriber must maintain a separate drug supply or the drug supply must be wholly owned by the professional director or some single prescriber.

CASA has pursued legislation that would have, among other things, expanded the board's authority to issue a clinic license to those surgical clinics that were operating either under a DPH issued license or are accredited by an approved agency or are Medicare certified. The board has consistently had a support position on such legislation.

Anne Sodergren introduced Bryce Docherty who represents CASA.

Mr. Graul asked if this is referring to the Plescia bill.

Ms. Sodergren confirmed that it is.

Mr. Docherty stated that he is the lobbyist for CASA. He indicated that they have been pursuing licensure of ambulatory surgery centers for the last three years, which the board has supported. CASA felt that is was important to clarify and expand those settings that would fall under the purview of the Board of Pharmacy for the purposes of drugs that are being dispensed and utilized in a non-inpatient environment. Their first two pursuits were vetoed by the Government, but not because of the drug dispensing aspect. These bills were vetoed because of the piece that spoke to the DPH authority to license ambulatory surgical centers. He noted that right now state licensure by the DPH to operate as a surgical clinic is permissive and not mandatory. Mr. Docherty explained that there are two legislative pursuits involved. The first is the surgical center piece, where they are trying to standardize the licensure criteria for surgical centers, as

there is currently none within the state law. In regards to the pharmacy aspect, CASA has been asking for the Board of Pharmacy's authority to issue a license to a surgical center, including those who are accredited by one of the four accrediting bodies approved by the Medical board, as well as those who are Medicare certified. Mr. Docherty noted the recent court ruling on Sept. 19th (Capen vs. Shewry) that determined that the Department of Public Health (DPH) has no jurisdiction over the licensure od surgical clinics in the state if they have some form of physician ownership. Mr. Docherty explained that the purpose of the letter submitted was to seek clarification from the board on the following:

- What are centers going to do if they want to seek a license from the board and they are no longer eligible for licensure?
- What are we going to do with those surgical clinics who have been licensed and who have obtained the clinic license from the board but are no longer eligible for licensure based on this recent court decision.

Mr. Docherty stated that currently the DPH is not renewing those licenses. He also noted that it is not only a requirement for the board issued clinic permit, but also a requirement in order to see Medi-Cal patients and for third party reimbursement.

Mr. Docherty explained that the letter was also submitted to advise the Licensing Committee that CASA is pursuing the current pharmacy-related portion of the bill AB 1574. The bill will be heard in Senate Health on June 25th. They are guardedly optimistic and are requesting support from the board.

Ms. Herold clarified that, by law, the board cannot issue a new permit, and can only renew a clinic that is already licensed with us.

Stan Weisser asked if there are many clinics affected by this issue. Mr. Docherty indicated that it is affecting many clinics.

Mr. Graul asked for clarification that AB 1574 is only addressing the pharmacy portion of the prior bill, and was concerned that the board would be issuing permits to unlicensed facilities.

Mr. Docherty explained that the board issued clinic permits is only currently to a DPH state-licensed surgical clinic, and they are attempting to gain obtain authority so that the board can provide clinic permits to those who are accredited by one of the four accrediting agencies or Medicare certified in lieu of being state licensed with DPH.

Steve Gray (Kaiser Permanente) asked how many accredited and/or Medicare certified clinics there are.

Mr. Docherty explained that it is unknown at this time.

Mr. Docherty stated that some accredited and Medicare certified ambulatory surgical clinics are wholly physician-owned entities and their clinics are regulated by their medical license.

Mr. Graul clarified whether the bill would make it mandatory for the surgical clinics to gain permits. Mr. Docherty stated that they would not.

Mr. Docherty stated that CASA is looking for an official response from the board on how the Capen decision will affect board issued clinics.

Ms. Herold stated that those currently licensed would not lose their ability to renew their permit, as we do not have grounds to remove them. She reiterated that we cannot address the issue of licenses for new clinics until there is a legislative fix.

Mr. Docherty requested written confirmation that the board will continue to renew the clinic permits.

Ms. Herold stated that the clinics are already aware of this, and that anyone with questions or issues can contact her.

Peter Kellison (Surgical Care Affiliates) stated that it is a very complicated environment and appreciates the board's support.

Ms. Herold noted that a clinic will still be able to operate regardless of the board's decision or ability to address the permit issue, and that it is simply a bit more complicated with physicians bringing in their own pharmaceuticals. It was noted that the item would be placed on the agenda for the July board meeting.

Dr. Gray asked when the permits of the surgical clinics expire.

Ms. Herold and Ms. Sodergren explained that the permits are renewed on a cyclical basis.

Dr. Gray pointed out that the Board of Pharmacy permit also entitles a clinic to obtain a separate DEA registration number, DEA forms, etc. Without that, it causes issues at a federal level as well. He also noted that a separate DEA registration is required for every facility where the drugs are stored, causing even more complication. Dr. Gray asked Mr. Docherty who will be issued the board-issued clinic license.

Mr. Docherty stated that the permit would be issued to the clinic, based on the ownership structure.

<u>Discussion with the California Pharmacists Association and California Society of Health-Systems Pharmacists on a Task Force to Evaluate Pharmacy Technician</u> Qualifications

Dr. Ravnan reported that this year the California Society of Health-System Pharmacists (CSHP) sponsored legislation to increase the requirements for an individual to become licenses in California as a pharmacy technician. This bill was pulled due to concerns vetted by key pharmacy stakeholders, with the intent of pursuing legislation again in 2009.

CSHP will be sponsoring stakeholder meetings to elicit recommendations and comments to refine the proposal for next year. The first stakeholder meeting is scheduled for June 25, 2008. Board staff will attend the meeting and report to the board at the July board meeting.

Mr. Docherty (representing CSHP) provided comments to the board on the topic. He stated that CSHP currently sees this as their "top" legislation priority. He indicated that there are approximately 50,000 licensed pharmacy technicians, and that the amount of licenses being issued is increasing rapidly. They feel that the requirements to obtain a technician license need to be strengthened. CSHP had proposed a bill that would require a pharmacy technician to pass the Pharmacy Technician Certification Board (PTCB) exam or other exam that is psychometrically sound, rather than it being one of four options as is the current law in order to obtain a license. The bill would also establish the requirement of 20 units of continuing education every two years for pharmacy technicians. Mr. Docherty stated that CSHP wants to ensure that pharmacy technicians are maintaining competency. CSHP also wants to ensure the bill encompasses all "houses" of pharmacy as well. CSHP is having their first stakeholder meeting on June 25th for further discussion. Mr. Docherty thanked the board for their involvement of the bill and indicated that CSHP is requesting the board to co-sponsor the bill next year.

Mr. Graul asked who is participating in the stakeholder meetings. Mr. Docherty indicated that it includes CSHP, CPHA, Kaiser, California Retailers Association (CRA), United Food and Commercial Workers Union, as well as anyone else who would like to attend. Assembly Member Bill Emmerson is sponsoring the bill and requested the meeting be held at the capitol so that he could be present for its first meeting.

Mr. Graul asked who is participating from the board.

Ms. Herold indicated that Ms. Sodergren would be attending, as Ms. Herold is unavailable.

Mr. Graul and Mr. Weisser both noted that they would be unable to attend the first meeting, but would like to be kept updated on the progress.

Chairperson Ravnan asked if work experience was discussed as part of the legislative proposal, since competency and technical skills are best obtained through repetition and hands-on work experience.

Mr. Docherty stated that there are numerous issues that need to be addressed related to standardized education and training, however their focus right now is on the licensing requirements as discussed.

Mr. Graul asked if there is still a shortage of pharmacy technicians in the state. Mr. Docherty indicated that there is a shortage of pharmacists, but was unsure if there is still a shortage of technicians.

Hank Hough shared an example of a case in Florida where a death resulted from pharmacy technician error. He stressed how this highlighted the needs for continuing education, as the consequences can be disastrous.

Ms. Rice asked what prompted the need for a bill. She also stated that studies have shown that continuing education does not necessarily enhance a technician's performance, and that work experience rather creates increased competency. She stated that required continuing education only increases the profits of the provider of the continuing education, and stressed that the board place serious consideration over the need for such standardized requirements before putting such requirements in place for technicians who make considerably less money than pharmacists. She stated that the bottom line on continuing education is that it is a good way of having a discussion amongst your peers, but she has yet to see anything that shows conclusively that continuing education increases and enhances performance. She feels that it shouldn't be something that is put in place simply because everyone else is doing it. She noted that this opinion is her own, and not necessarily that of UCSF.

Ms. Herold responded that the board did not take a position on the issue in one direction or the other.

Mr. Docherty provided a response to address the issue. He explained that CSHP and CPhA represent a fair amount of pharmacy technicians and that there was a lot of discussion from the technicians themselves regarding education. He pointed out that the technician involved in the Florida case was someone who did not pass the PTCB and was awaiting another opportunity to take the exam when the incident occurred. He noted an incident in Ohio, as well as the incident at Cedars-Sinai involving the Quaid twins, and the procedures neglected and errors made by the technicians involved. In terms of continuing education, it is a need for CSHP to "get ahead of a curve" in case something else like this should happen in California.

Ms. Rice responded with her concern over pharmacy technicians being trained or supervised by other pharmacy technicians, and questions the involvement and responsibility of the pharmacist.

Mr. Docherty responded that those comments speak to the need for the bill as well, as pharmacists need to be able to place more responsibility on the technicians and know that there is a certain level of competency there as well, rather than trusting on one of the four requirement options having been completed.

Ms. Rice responded by requesting that CSHP look at the literature regarding continuing education.

Dr. Steve Gray stated that CPhA is also concerned about the issue discussed and lack of competency requirements of technicians at this time. They do not find any evidence to support that passing the PTCB improves performance, and that there may be better ways to ensure performance. He also suggested to the board to look at the ratios as well as the varying environments technicians are employed in and how they are supervised. Dr. Gray suggested the consideration of having different types of technicians and/or how the technicians are utilized within the various entities and work environments they are employed in. He also brought up the issue of a lack of minimum age requirements with regard to technicians, including the fact that background checks cannot be conducted when technicians are under the age of 18, which often includes minors who have dropped out of high school for various reasons that are unknown. Dr. Gray also discussed technicians being utilized outside of pharmacy settings.

Mr. Weisser discussed the interaction between technicians and customers, and that enhanced education would be a benefit to the pharmacies as a whole. He stressed that he can only see benefits to providing the need for those technicians to gain the continuing education that they may not otherwise have and enhance their performance with relation to customer interaction.

Ms. Rice responded that the technicians that voluntarily pursue continued education are the ones who want to learn and will succeed in their education, and that those who are forced to attend continued education will not necessarily see the benefit and take advantage of it.

Heidi Barsuglia (CRA) stated that they are attending the stakeholders meeting. She pointed out the differing views on this proposal, and stated that it is premature for the committee to recommend to the board to co-sponsor this legislation until we see what the legislation may look like.

Ms. Herold advised the board not to pursue sponsorship at this time, as it is premature. She stated that the board should wait for the stakeholders to work out the details of the proporsal. She pointed out that she felt it was a wise decision by the author to pull the bill back.

"Cookie" Quandt (Long's Drugs) stated that there is a shortage of technicians, especially in very rural areas. She also commented on the technician schools mentioned by Dr. Gray. She stated that they have not had success in gaining

technicians from those schools, as they are often high school drop-outs and end up with drug diversion incidents within their pharmacies when employed.

Mr. Weisser asked if their program has an ongoing education program for their technicians.

Ms. Quandt stated that it involved classroom training as well as on-going training provided by pharmacy managers. There are also manual requirements, which the technicians must review on an annual basis. She concluded by saying that training is required before they go into the pharmacy in order to understand the requirements.

Mr. Graul indicated that he agrees with the continuing education (CE) proposal, but wants to study the details of the proposal further before having an opinion. He did note that if there is a formalized CE requirement, it generates more technician centered CE, which there isn't much of right now. He added that as a consumer protection agency, the board should look at the quality of technicians and assist the legislature in coming up with some requirements that ensure the quality of technicians in California is superior.

Mr. Weisser agreed with the comments given by Mr. Graul.

Bill Young (Alameda County Pharmacists Association) provided feedback from local pharmacy owners and managers. He stated that that there does not appear to be a shortage of licensed pharmacy technicians looking for employment, however there is a shortage of qualified, promising technicians that pharmacists want to hire.

The board has no recommendation on the proposal at this time. Two members of the committee would like to be a part of the task force. Ms. Herold commented on the need for numerous meetings to work through the details of the bill and address the concerns by all stakeholders. Mr. Docherty stated that they would have as many meetings as needed in order to exhaust all the issues.

<u>Discussion to Amend 16 CCR Section 1728 to Increase the Number of Intern</u> <u>Hours that Can Be Earned Outside of a Pharmacy</u>

Dr. Ravnan stated that under current law, an intern must possess 1,500 hours of intern experience under the supervision of a pharmacist before he or she can be made eligible to take the pharmacist licensure examinations.

More specifically, board regulations specify that a minimum of 900 hours of pharmacy experience must be earned under the supervision of a pharmacist in a pharmacy. The remaining 600 hours can be granted for experience under the supervision of a pharmacist if substantially related to the practice of pharmacy, but not specifically within a pharmacy. California pharmacy students typically earn the 600 "discretionary" hours for school-required experiential training (clinical clerkship).

At the March 2006 Licensing Committee Meeting, pharmacy students from USC and other pharmacy schools presented a proposal requesting that the Board of Pharmacy amend its requirements that allow for an additional 400 hours (for a total of 1,000 hours of the required 1,500 hours required) that an intern can earn for pharmacy-related experience (under the supervision of a pharmacy) outside a pharmacy.

According to the students, opportunities for pharmacists have expanded beyond the traditional areas of community and hospital practice settings. Many students would like the opportunity to gain experience in the pharmaceutical industry, managed care, regulatory affairs and association management, but are unable to do so because they cannot earn intern hours for this experience, which impedes their experience as students and future development as pharmacists.

At the December 2006 Licensing Committee Meeting, pharmacy students provided a presentation highlighting the additional areas that interns could pursue if the intern hours experience requirement was more flexible. They cited statistics indicating the benefit that redirected students could provide to health care and that the proposal firs the board's mission.

Discussion at the December 2006 meeting included a possible increase of 400 hours of the intern experience requirement, to total 1900 hours, to permit such additional experience. Discussion also included the need for students to thoroughly understand the workings of a pharmacy, and why such experience is so important to a pharmacist's future as a supervisor of pharmacy functions and personnel and that without a solid understanding and actual experience in such environments, pharmacists will have a difficult time because core experience in pharmacist is lacking.

At the conclusion of the December 2006 meeting, the committee determined that it was premature to move forward with the students' proposal given that concurrent with this request, the Schools of Pharmacy in California were undertaking an initiative to establish core competency assessment of basic pharmacy intern skills. (The ACPE guidelines detail the advanced pharmacy intern skills competencies.) At the request of UCSF, the board sent a letter supporting the results of the initiative.

As the development of these core competencies were completed, President Schell requested that the Licensing Committee revisit the request to amend the intern hours requirement.

President Schell commented that this issue that was brought to him from a student at Loma Linda University practicing at an ambulatory care pharmacy site, and was told his hours would not be included because he was not practicing at a licensed pharmacy as the law requires. President Schell pointed out that he has not necessarily been in support of this concept in the past because he does not feel intern hours should be included from certain entities such as manufacturers, etc. The example provided of this student, however, where someone is under the supervision of a licensed pharmacist, seems

appropriate. He highlighted that pharmacists no longer have to be working in a licensed pharmacy in order to practice pharmacy, and that the board should alter the intern hour requirements to match what we've done with licensed pharmacists and allow students to obtain those types of experiences.

Ms. Herold asked how the board would be able to determine whether someone's experience in a non-pharmacy is substantially related to the practice of pharmacy. She gave examples of recent inquiries of pharmacologists requesting intern hours for preparing lectures for students in the area of pharmaceutical education. In that situation, that would be within the board's discretion, but they are not working within a pharmacy or in the direct supervision of a pharmacist. She stated that a lot of these will become "line calls" for the board and that, without clear regulations, would become difficult to decide upon fairly and consistently. Ms. Herold noted that the board does their due diligence with regard to acquired intern hours and proper authorized signature of licensed pharmacists for those hours, but they also accept the out-of-state intern hours with no knowledge of where they were truly obtained.

President Schell remarked on the protocol from the past, which was to require affidavits indicating specific activities that must be completed by the intern in order for the pharmacy supervisor to approve, and encouraged the board to consider revisiting the need for those again so that the board had clear guidance on what was required for the legitimacy of intern hours. President Schell felt that there are ways to work around the situation and find solutions, and to not allow intern hours to work in environments such as ambulatory surgical clinics could create disparity in what should be considered an important pharmaceutical education.

Dr. Gray stated that Kaiser has had a lot of discussion around this subject over the last few years. Kaiser feels that the board needs to consider recharacterizing what it means by "under the supervision of a pharmacist" and what type of practice of pharmacy should be included. He noted that also means the board would need to know what to exclude in that definition process, which is not always an easy or painless thing to do. He gave examples of where and how the 900 versus 600 intern hours could be accumulated and "right versus wrong" ways to gain those hours. Dr. Gray stated that they have found that too many of their graduates are not ready to become dispensing pharmacists when they leave school. Due to the pharmacist shortage and the economy, Kaiser often sees the new graduates working alone and during late evening hours, without the proper supervision and mentoring opportunities that they need. They are now implementing their own intern rotation process within Kaiser, allowing them a more complete experience over two to three years during their internship.

Ms. Rice stated that the board should include the new American Council on Pharmaceutical Education (ACPE) requirement of an additional 300 hours of Introductory Pharmacy Practice Experience (IPPE) into the continued discussion and regulation as well. She also agreed with Dr. Gray's comments regarding flexibility in the regulations. She pointed out that a student can graduate with six weeks in a community

setting, and that we should take thorough consideration with regards to lowering that requirement.

Mr. Weisser reiterated that it is critical that they have experience in working with the patients.

Chairperson Ravnan discussed her thoughts with the 900 hours and stated that she does not feel that it is too much time to require. She pointed out that there are advantages for students to be working directly with patients and using their cognitive skills, as well as the unique experience within the practice of pharmacy of which they can learn from other professionals. She stated that she would hate to see them lose the opportunity to gain those skills as well as skills assessments.

Mr. Graul asked if the 300 hours of IPPE is within the first year. It was clarified that it is within the first two years, and that they would have their intern license by then. Mr. Graul asked if the 300 hours could be used for the 1500 hours.

Ms. Rice clarified that they cannot be paid for the 300 hours, whereas the 1500 hours of intern hours are paid.

Mr. Graul asked how difficult it is for the intern to obtain their 1500 hour requirements.

Chairperson Ravnan asked for clarification on the 900 hours and if they are non-paid. It is not clarified within the law. It is concluded that the school can thus approve the hours if they were earned in early experience in a pharmacy. An affidavit would be required, signed by the pharmacy in which they earned the hours.

Dr. Gray discussed the wording of a form in the past with reference to the phrase "employed", which gave the impression that the hours then needed to be paid. Clarification has been provided by the board since then, indicating that the hours do not need to be paid hours. There has been argument by ACPE on whether it is appropriate to be paid for their IPPE hours, but legal action has been taken by them on a school of pharmacy.

Ms. Herold pointed that there is a cap in the pharmacy law that you can only issue the intern permit for six years, but the board is seeing some candidates entering in with programs that are longer than six years.

Mr. Weisser stated that the introduction of pharmacy practice experience does not involved students with patients and isn't sure it's very experiential.

Ms. Rice stated that it depends on the environment and type of training the student has had. She reiterated that it is still a burden for the first and second year students.

Bob Ratcliff made the comment that it doesn't seem to make sense to have the students put so much effort into earning up the 900 experiential hours, and not focus on the 600

hours offered by the school. Mr. Ratcliff suggested to place more ownership on the school to incorporate the training they feel is needed for more well rounded students within the 600 hours the school provides. He stated that part of the issue for the graduates coming out of school is that they haven't worked long enough in drug distribution in order to understand all the nuances that are involved.

Chairperson Ravnan added that when she was teaching, her students did a regulatory rotation and received credit for that towards their 600 school hours, pointing out that the schools do in fact have that discretion to offer such electives.

Mr. Graul commented on the possibility of increasing the hours to an additional 400 hours as previously suggested.

Ms. Rice raised the issue of the additional 300 hours for IPPE as discussed prior.

Chairperson Ravnan pointed out that the 300 hours can be included in the 400 total, and can be paid or unpaid. She clarified that it would not be an additional 700 hours, but only 100.

Dr. Gray stated that the board should be cognizant of the changes at the national level. He said that there are discussions involving mandatory one-year of post-graduate residency being required by law. He questioned whether the required hours in place today are enough for the board to grant a license and allow students to go to work in pharmacies. He stated that he would rather see a student earning their 600 hours in an environment working side-by-side with a pharmacist in a critical care setting.

Mr. Graul responded that it comes down to a balance between a student getting a lot of patient care experience in a non-traditional environment, yet still needing the experience to handle the setting of being alone after-hours in a dispensing pharmacy setting.

Dr. Gray clarified that he is still in favor of the 900 hours in a dispensing pharmacy setting. He doesn't feel that those 900 (or even 1500) hours in a dispensing pharmacy (only) may not be enough to prepare them.

It was clarified that Dr. Gray is in favor of increasing the intern hours requirement or ensuring that the current hours are obtained in appropriate settings that allow for well-rounded experience and competency needed.

Ms. Herold stated that the discussion could go to the board with or without a recommendation.

Ms. Rice reiterated that the board should be monitoring the activity and decisions at the national level before moving forward.

Mr. Burgard stated that it is unenforceable as the law reads now. He shared his concern over the lack of specifics with how interns are required to gain their hours.

Ms. Weisser suggested that we take no action at this time and look to the direction of the board and chair for further input.

MOTION: Table any action at this time to alter the intern hours requirement.

M/S: JB/HH

APPROVE: 4 OPPOSE: 0

<u>Discussion of the Ability for Pharmacy Applicants to Pursue Board Licensure</u>

<u>Concurrent with Department of Health Care Services (DHCS) Provider</u>

<u>Recognition and Drug Enforcement Administration (DEA) Registration</u>

Christine Soto provided a presentation on the subject by outlining the application process and discussing how applicants can file applications with other agencies simultaneously.

Ms. Soto provided the board Web site and explained that applicants download a pharmacy application at the site. She indicated that applicants should copy their application and include it with concurrent applications submitted to the Department of Health Care Services (DHCS) and Drug Enforcement Administration (DEA) demonstrating that the entity is also seeking board licensure. This will allow applications to be processed concurrently by all three agencies in order to minimize impact and avoid delays.

Ms. Soto reviewed the licensing application process, including the time frame for each stage of the process. She made note of the reasons for delay in some applications, which can be due to deficiencies in the application, research of an applicant's criminal history, etc.

Ms. Sodergren added background on the reason for the topic as an agenda item for discussion. She explained that there has been some concern by some applicants because they are unable to get their DEA registration number or Medi-Cal provider number from the DHCS until they are licensed by the Board of Pharmacy. It was brought to the board to have the Licensing Committee and board staff review the current process and determine the reason for the delay for some applicants versus others. The recommendation by the licensing staff is for applicants to provide a copy of the application submitted to the board when submitting their applications to DHCS and DEA. The DHCS and DEA will to process their registration number and provider number applications with the knowledge that a license is being sought by the Board of Pharmacy as well. However, it is important to note that the DHCS and DEA will still wait to provide the numbers until the license is approved by the Board of Pharmacy. Applying concurrently to all three agencies, however, will help to avoid delays with DEA and DHCS.

Ms. Herold explained that this is very routine but found that some entities were unaware of the process and ability to apply concurrently. She stated that the board would include this information in a future Script newsletter.

Mr. Graul asked if this information is included in the FAQ section of the website. Ms. Soto stated that it is not, but should be included.

There was brief discussion on pre-opening inspections conducted prior to licenses, registration and provider numbers in place.

Ms. Soto stated that the licensing department does make efforts to assist applicants who experience delays in the process by contacting DHCS and DEA as needed.

Dr. Gray suggested that the board include information in the newsletter and FAQ website section indicating that you cannot obtain your NPI number at the same time.

Status Report to the Committee on Continuing Education Audits

Chairperson Ravnan indicated the Business and Professions Code section 4231 requires that the board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that he or she has completed 30 hours of approved continuing education during the two years preceding the application for renewal. This section also exempts this requirement for the first renewal of a pharmacist license. Effective in 2006, this section was amended to state that the board would not renew a license if proof is not provided and instead requires the board to issue an inactive pharmacist license.

Since 2006, the board has used its enforcement discretion and has not fully implemented this requirement. Rather, the board is randomly conducting continuing education audits on a monthly basis. Over the last year, these audits have revealed that approximately 12% of pharmacists audited provide false information on their renewal. As a result, the board completes an investigation substantiating the violation and a citation and fine is issued.

In addition to these audits, the board sends an average of 20–25 letters to pharmacists monthly who fail to certify the completion of the required continuing education. Because of delays in the programming changes necessary to fully implement the changes made to these requirements in 2006, the board has been handling much of this process manually. Board staff continues to advocate for the necessary programming changes required to the system. Absent the programming changes, board staff will begin to manually issue inactive pharmacist licenses to those individuals who fail to provide proof of their continuing education as required.

Ms. Herold explained that CE audits have been consistently conducted over the last year based on pharmacist license renewals. The audits are done at least six months

after the renewal period, to avoid confusion about when the audit was completed. Cite and fines are issued to those who are unable to provide proof of completing their CE. Ms. Herold pointed out that 12% non-compliance is about half of the prior years' audit. The prior audit of 2005-2007 conducted reflected 33% non-compliance. She noted that the law allows the board to change their pharmacist license to inactive if compliance of CE cannot be proven. Ms. Herold is advising pharmacists that the board will be diligently taking action as is appropriate on those non-compliant pharmacists.

Ms. Sodergren noted that, in addition to the audit process, the board would send a notice when CE has not been included on the renewal application. If a notice is sent, and the pharmacist does not respond with documented proof, the pharmacist will be changed to inactive status.

Mr. Weisser asked how a pharmacist could then be removed from inactive status.

Ms. Herold responded that the pharmacist would need to pay the fine and then provide proof of 30 hours of CE since the time of the last renewal.

Mr. Weisser asked about pharmacists that do not have their full CE completed.

Ms. Herold responded that the board wants the pharmacists in compliance, but that there will be a consequence.

Mr. Weisser asked why pharmacists are not required to send copies of their CE completion to the board. Ms. Herold responded that the paperwork would be overwhelming for the board and staff, and would require an increase in fees to accommodate the paper overload.

Ms. Quandt asked for clarification that the board audits 20-25 pharmacists at least six months after their renewal. She confirmed that it is only 1% of the total pharmacists.

Ms. Herold agreed that it is extremely low, but that it is just enough to keep the pharmacists alert.

Ms. Quandt asked about advice for those pharmacists who failed to sign the affidavit indicating that they have completed their CE and want to be able to renew as soon as possible.

Ms. Herold responded that the pharmacists should download the renewal form on the Web site and be sure to sign the statement under penalty of perjury that they have in fact completed their 30 units of CE. She indicated that they should also include their documented proof of CE as well, as it will ultimately be requested.

Ms. Quandt asked if it is appropriate to recommend to the pharmacists in this situation to go to the board office to submit their documents.

Ms. Herold indicated that it would be appropriate as well, but that the documents may or may not be reviewed immediately at that time.

Discussion also included the specifics of how a pharmacist can verify the status of their records in relation to their CE, as well as how an employer can determine whether a license has been cleared by viewing the board website.

Ms. Herold reiterated the importance of making sure all pharmacists are earning their CE.

Dr. Gray asked for clarification regarding whether a pharmacist is employable when inadequate CE is indicated.

Ms. Sodergren provided an explanation, indicating that the CE inadequate status occurs when it is time for the pharmacist to renew their license. The license could be changed to an inactive state if the pharmacist fails to submit continuing education are required.

Dr. Gray asked about the situation where a pharmacist is renewed and is later audited. He asked what action is taken if it is determined that the pharmacist does not have adequate CE completed.

Ms. Herold stated that the board would issue a notice to the pharmacist of the shortage in CE and provide 30 days for the pharmacist to complete their missing CE hours, as well as provide proof of the completed hours. A fine will also be issued for non-compliance.

Ms. Sodergren added that SB 1779 does allow the board to change a pharmacist's license to inactive if they are found to be non-compliant of CE hours at the time of an audit.

Ms. Herold added that there would still be a notification process prior to any action taken. She reiterated again that the focus is to get the pharmacist in compliance and completing their CE hours.

Dr. Gray asked for clarification that a pharmacist may complete their deficient hours during the 30-day allotted period.

Ms. Herold confirmed.

Ms. Sodergren noted that those hours, however, cannot be counted for the current renewal period, and would only apply to the prior renewal period where the hours were missing.

Ms. Quandt raised the concern over needing to monitor the pharmacist's license status on a monthly basis in order to verify any pharmacists that may have been converted to inactive status due to inadequate CE.

Ms. Herold noted that it may be a disciplinary action for the employer.

Ms. Sodergren indicated that this is the case for any pharmacy and that a pharmacist can voluntarily make changes to affect their pharmacist license as well. She noted that the pharmacist license status on the Web site is only a snapshot in time.

<u>Quality Assurance Review of the California Practice Standards and Jurisprudence</u> <u>Examination for Pharmacists (CPJE)</u>

Chairperson Ravnan stated that during the public comment portion of the April 2008 board meeting, the board heard comments from Jennifer DeLany regarding the board's Quality Assurance (QA) review of the California Practice Standards and Jurisprudent Examination for Pharmacists (CPJE). Counsel advised the board that no action could be taken during that meeting and as such the board decided to place this discussion on a future agenda to allow for board discussion. As this matter is related directly to licensing, it is being brought before the Licensing Committee for discussion.

The board contracts with a psychometric firm who provides the board with expert guidance on the appropriate administration and scoring of the CPJE, including quality assurance assessments. The contractor determines the criteria that need to be met in evaluating the examination's performance before candidate scores are reported. Board staff recognizes the consequences that such reviews have on candidates that work closely with the contractor to release scores as soon as possible.

The CPJE is an essential function of the board's licensing program and decisions are not done arbitrarily or capriciously but with deliberate care and with consultation from experts in the field of exam review, testing and validation.

Ms. Herold added that the exam vendor determines when the board can release the exam scores. This is done to protect the integrity of the exam process. It is also done because the exam consultant is responsible for defending the validation of the exam in the case of a lawsuit.

Dr. Gray asked when the results of the exams were released from the most recent QA period.

Ms. Herold responded that the results were released by June 3, 2008.

Mr. Graul asked how often the QA period occurs.

Ms. Herold indicated it is typically done about three or four times per year, but not necessarily quarterly.

Mr. Graul asked about the time delay involved.

Ms. Herold says it is typically conducted until 400 applicants have completed the exam, but that the board allows the vendor to determine the time it feels necessary to complete the validity. It was noted that during the "off season" where less applicants are taking the exam, the QA period might take longer.

Bill Young (Kaiser Permanente) indicated that students are highly anxious when their test results are held for the extended period, and asked if it is possible to work with the vendor to allow for advance notice of the QA period for the consideration of the students.

Ms. Herold noted a similar incident last year when the board was changing exam vendors. The students were advised of the vendor change, which resulted in a "rush" of students trying to take the exam before the vendor change. This caused a major reduction in exams being taken after the vendor change, thus delaying the next QA period even more. Ms. Herold stressed the negative effects of providing forewarning of a QA, including a significant shift in students being willing to take the exam.

President Schell reminded everyone that, prior to 2004, the board could only offer exams twice a year.

Ms. Herold stated that the board is sympathetic to the anxiety and stress of the students. The board however, needs to ensure that, with public protection as the core, the exam is a valid assessment of whether or not each pharmacist applicant is minimally competent.

Competency Committee Report

Chairperson Ravnan stated that the Competency Committee has had regular meetings, and has provided a proposal to the Licensing Committee.

Request to Grant Continuing Education Credits for Participation on the Competency Committee

Chairperson Ravnan noted that the Competency Committee is a subcommittee of the board's Licensing Committee. Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). A committee member term is generally about eight years.

Annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. Each two-day committee meeting consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Committee members also participate in 2-4 writing assignments based on the examination

development need. Committee members spend approximately 50-80 hours preparing for and attending committee meetings on an annual basis in addition to multiple writing assignments.

The Competency Committee requests board approval of six hours of CE earned annually for Competency Committee member participation.

A comment was included that a regulation change will be necessary to allow the board to award the CE should it approve this request.

Chairperson Ravnan noted that she was a member of the competency committee prior to joining the board. She indicated that it was a grueling task at times, and although there was compensation for the duties, it was a humbling experience. She added that the experts on the panel are in fact true experts who had to do above and beyond the CE credits required in order to have the discussions involved for exam preparations. Chairperson Ravnan stated that she was perplexed that they would request almost half of their CE hours to be counted by way of the competency committee participation, as there is a need for additional higher education in their level of expertise required as the members of the committee are held at a higher standard. Chairperson Ravnan strongly disagreed with recommending the approval of the six hours of CE to the board.

Ms. Sodergren spoke on behalf of the committee and noted that the committee would be open to the number of hours granted, and that the quantity of six only came from being consistent with the amount of hours earned for pharmacists who attend a public board meeting.

Ms. Herold publicly acknowledged the hard work and efforts of the Competency Committee members. She explained how diligently the committee works on the exam questions and process. She noted, however, that the committee members do agree to serve on the panel and receive compensation for doing so. She added that, by giving them CE for doing something they would otherwise do, we are exempting them from a requirement to earn CE. Ms. Herold also agreed with Chairperson Ravnan's comments in that the committee members are expected to be subject matter experts who need to maintain the higher education level expected of them by way of higher level learning. Ms. Herold suggested that, if moving forward with the recommendation, compensation then be reduced in lieu of the credits.

Mr. Weisser asked what the compensation is.

Ms. Herold responded that it is \$30 per hour plus reimbursed state travel expenses.

Chairperson Ravnan added that being on the committee and being able to conduct discussion with other panel experts is a benefit and a rewarding experience, and that it is an honor to be on the committee.

Mr. Burgard agreed that the tasks performed by the committee are very grueling in terms of the extensive process involved in determining exam questions. He stated that he is in favor of whatever can be done to assist and support the members of the committee.

Ms. Weisser stated that granting the 6 hours of CE would seem to be a "small perk", although the compensation is also significant.

Chairperson Ravnan is concerned that this will open the floodgates for other professionals in the pharmaceutical industry to request CE. She gave the example of educators requesting CE for hours placed in instruction.

Mr. Graul stated that the reason individuals choose to sit on committees is not for the purpose of acquiring CE. He added to Chairperson Ravnan's concerns about other committee members then being able to earn CE for their time spent on a committee as well. He acknowledged the hard work conducted by the committee.

President Schell asked how difficult it is to obtain members to sit on the committee.

Ms. Herold responded that it is not too difficult, but has varied in terms of recruitment results in the past. She noted the requirements to qualify for the committee, as well as the need to limit the candidates to varying types of professional background and areas of specialty.

President Schell brought up the issue of retaining and recruiting members for the committee for the future.

Ms. Herold suggested the topic of CE to the October Board Meeting agenda. In the interim, the Competency Committee members will be surveyed (at their August committee meeting) to determine how many are in favor of the CE credit as well as any issues that may need to be addressed. She felt that it is important to determine how crucial the issue of CE units is to the committee before pursuing any further.

Dr. Gray suggested the board to research what other boards do regarding CE credits and their competency committee.

Ms. Herold pointed out that there isn't necessarily a comparable structure because other boards do not necessarily have state exams.

Review and Discussion of "Standards and Guidelines for Healthcare Surge During Emergencies" Report

Ms. Sodergren informed the committee of standards developed by the Department of Public Health Services to be used as training material by local agencies, government,

and health care providers to get them thinking about disaster planning. The board is sharing this as an available tool for disaster response. The memo that was provided to the committee provides a link to the DPH website where the materials can be downloaded.

Ms. Herold added that the Governor's office spent millions of dollars creating the report as well as extensive training in conjunction with preparing for natural disasters.

Ms. Herold discussed the current state with regard to the large fires currently spreading throughout California. She stated that a pharmacy in Santa Cruz requested that the board activate the emergency response plan out of concern over patients presenting at the pharmacies needing medications filled due to leaving their prescriptions when evacuating their homes.

Ms. Herold asked the committee for guidance on when the board's emergency response plan should be put into affect.

Chairperson Ravnan asked about the form of communication in the event of enacting the emergency response plan.

Ms. Herold indicated that it would be advised via a subscriber alert. She also added, however, that if the alerts occur too frequently they can lose their impact of seriousness.

Dr. Gray asked if there is a bill that will address the issue.

Ms. Sodergren and Ms. Herold confirmed that AB 2756 will address this.

Dr. Gray pointed out the complexity of how to provide guidelines in the event of the response being enacted, including the geographics involved based on where the disaster is taking place versus where the patient goes to fill the prescription. He also indicated that there is confusion over how emergency refills are to be handled, including the fact that a patient can have a prescription filled at a pharmacy different than where it was originally filled.

President Schell noted that the confusion was an issue last October in San Diego during the fires in that area.

Ms. Herold added that the board did send out three subscriber alerts at that time.

Mr. Weisser asked how a pharmacist finds out about the emergency response plan during the time of a disaster.

Ms. Herold responded that it would be from the Office of Emergency Services.

Mr. Graul shared his experiences with having difficulty trying to get prescriptions filled for patients at various pharmacies during the fires last October. He also pointed out the

amount of time before residents are sometimes allowed back into their homes during disasters such as fires, and suggested not to place an arbitrary time frame on the emergency response plan.

Ms. Herold stated that it may be time for the board to discuss the need to redefine the specifics of the disaster response plan.

Discussion continued regarding the evacuation of small groups of residents in remote areas and issues with those families obtaining needed medication refills with various situations (no bottle, can't reach doctor, etc).

Mr. Hough stated that this highlights the importance of reminding patients to keep the name of their medications they are taking within their purse or wallet.

Dr. Gray shared information on a new program where patients can have their medical history and list of prescriptions on a database to access from any computer anywhere.

Mr. Hough responded that it still would not resolve the problem when they do not have access to a computer in a large disaster situation.

Mr. Graul emphasized that each situation will require pharmacists to exercise professional judgment on a case-by-case basis. The pharmacist can always follow-up with the prescribing doctor once the emergency is over.

Mr. Weisser noted that after many years in the industry, pharmacists are often skeptical.

Discussion ensued regarding needed specifics and parameters for pharmacists in the case of a natural disaster.

Mr. Graul stated that pharmacists may need direction to make judgment calls within reasonable professional limits, as long as they document their actions properly.

Ms. Herold responded that it is clearly documented in the disaster response policy in that sense.

Mr. Hough reiterated the need to place responsibility on the patient to carry their prescription information with them. He felt that this would eliminate a lot of the issues discussed today. He suggested a card that prescription information would be written on so that it is easy to carry in a purse or wallet.

Mr. Graul suggested continuing to remind the pharmacists on an ongoing basis of the guidelines to make professional judgment in emergency situations, document the incident, and follow up.

Review of Strategic Plan for 2008/09 for the Licensing Committee Goals

There was no discussion on the 2008-2008 Licensing Committee Strategic Plan.

Public Comment for Items Not on the Agenda

No public comments were provided.

The Meeting was adjourned at 4:07 p.m.

Attachment 8

Licensing Statistics 2007-08

	JUL	AUG .	SEP]	OCT]	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
APPLICATIONS													
Received	169	115	108	97	95	76	95	117	95	232	433	405	2037
Pharmacist (exam applications) Pharmacist (initial licensing applications)	205	42	361	71	156	136	67	72	82	67	22	136	1417
Intern pharmacist	52	287	316	446	51	61	123	110	113	119	82	58	1818
Pharmacy technician	604	590	634	593	587	501	665	600	609	722	625	879	7609
Pharmacy	49	48	25	42	27	43	18	19	26	21	25	17	360
Sterile Compounding	11	3	11	4	4	3	4	7	7	7	5	8	74
Clinics	13	5	8	12	4	4	1	19	6	13	12	2	99
Hospitals	5	0	0	5	3	4	0	0	3	0	1	0	21
Nonresident Pharmacy	8	6	6	6	7	6	5	10	1	8	10	2	75
Licensed Correctional Facility	0	0	0	0	0	o	0	0	0	0	2	2	4
Hypodermic Needle and Syringes	1	3	0	0	o o	0	0	1	0	4	3	1	13
Nonresident Wholesalers	9	10	6	10	10	15	3	4	7	12	6	11	103
Wholesalers	3	5	4	4	2	5	3	3	5	3	7	7	51
Veterinary Food-Animal Drug Retailer	0	0	0	2	0	0	0	0	0	0	0	0	2
Designated Representatives	54	33	24	34	41	19	27	48	52	58	27	47	464
Issued							ı				I	Т	
Pharmacist	195	58	359	72	155	131	56	84	80	63		109	1386
Intern pharmacist	82	287	268	497	55	28	64	52	97	86	81	57	1654
Pharmacy technician	684	629	267	662	553	544	890	575	632	520		680	7118
Pharmacy	27	53	34	32	17	37	100	29	20	20		31	427
Sterile Compounding	1	5	8	2	2	2	31	13	5	1	6	0	76
Clinics	7	10	5	6	9	0	36	6	9		11	5	106
Hospitals	2	6	0	3	1	1	6	3	0		1	1	31
Nonresident Pharmacy	1	3	11	8	5	4	9	3	2	5	<u> </u>	4	59
Licensed Correctional Facility	0	0	1	0	0	0	0	0	0			2	3
Hypodermic Needle and Syringes	1	0	1	3	1	0	0	0	0			1	8
Nonresident Wholesalers	6	4	11	8	7	4	18	5	7	4		13	97
Wholesalers	6	2		6	3	2	12	2	7	6		1	59
Veterinary Food-Animal Drug Retailer	0 41	0		0 42	1	0	0	0	0		ļ	0 25	1 417
Designated Representatives	41	26	36	42	41	20	63	23	15	38	47	25	417

^{*}Calstars reports not available

Board of Pharmacy Licensing Statistics - Fiscal Year 2007/08

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pending*	·												
Pharmacist Examination	u/a	u/a	1225	1208	1117	892	614	780	740	771	1178	1409	1409
Intern pharmacist	u/a	u/a	109	239	219	252	297	334	312	292	351	334	334
Pharmacy technician	u/a	u/a	739	1298	1034	1137	836	799	548	823	784	1170	1170
Pharmacy	u/a	u/a	172	78	66	73	77	60	71	68	66	60	60
Sterile Compounding	u/a	u/a	60	48	51	53	40	42	36	41	52	41	41
Clinics	u/a	u/a	77	46	45	60	56	56	57	63	71	68	68
Hospitals	u/a	u/a	22	15	12	16	19	17	20	14	15	17	17
Nonresident Pharmacy	u/a	u/a	58	51	52	50		56	61	62	59	67	67
Licensed Correctional Facility	u/a	u/a	0	0	0	0	0	0	0	0	2	2	2
Hypodermic Needle and Syringes	u/a	u/a	7	7	5	7	7	7	7	8	11	10	10
Nonresident Wholesalers	u/a	u/a	129	126	121	136	127	124	121	118	92	88	88
Wholesalers	u/a	u/a	37	32	31	35	35	34	31	30	23	27	27
Veterinary Food-Animal Drug Retailer	u/a	u/a	2	5	2	3	5	5	5	5	5	5	5
Designated Representatives	u/a	u/a	160	157	150	153	171	192	192	127	136	146	146
Change of Pharmacist-in-Charge							1						
Received	74	165	88	164	123	100	110	121	62	236	92	194	1529
Processed	148				1	127	119	124	129	180	55	187	1477
Pending	33				165		129	126	59	115	152	159	159
College State Stat		1											
Change of Exemptee-in-Charge						,		200					
Received	5	14	11	27	10	23	15	8	9	7	8	19	156
Processed	13	 	 	29	8		9	5	3	1	2	0	101
Pending	21	56	60	58	60	80	86	89	95	101	107	126	126
Change of Permits	37	191	11	5	3	8	57	62	54	46	60	43	577
Received	18	t		23	2		8	9	14	135	40	192	446
Processed	119	 	 		303		356	409	449	360	380	231	231
Pending	119	1 310	1 320	1 302		1 307		703	773		550	201	201
Discontinuance of Business													
Received	17	19	19	32	54	18	15	17	23	31	12	58	315
Processed	28	22	19	2	52	10		0	0	82	56	45	316
Pending	3	0	0	30	32	40	55	72	95	44	0	13	13**

^{*}Calstars reports not available

Board of Pharmacy Licensing Statistics - Fiscal Year 2007/08

	JUL	AUG	SEP	OCT	NOV	DEC	NAL	FEB	MAR	APR	MAY	JUN	FYTD
Renewals Received													
Pharmacist .	1429	3074	1352	1512	1107	1547	1421	1357	1274	1057	421	1382	16933
Pharmacy technician	1724	4015	1740	1924	1658	1949	1954	1974	1963	1554	794	1946	23195
Pharmacy	609	636	318	511	91	691	296	1229	643	134	759	187	6104
Sterile Compounding	9	63	12	32	8	11	20	18	11	20	1	19	224
Hospitals	27	28	25	113	27	35	64	43	19	26	2	29	438
Clinics	46	184	68	82	31	64	106	83	90	84	34	72	944
Nonresident Pharmacy	18	40	14	17	15	15	29	30	19	22	9	21	249
Hypodermic Needle and Syringes	12	44	16	33	16	26	32	31	14	14	5	23	266
Nonresident Wholesalers	19	65	28	39	16	31	39	51	34	37	15	30	404
Wholesalers	19	108	32	38	21	38	48	35	30	26	18	42	455
Veterinary Food-Animal Drug Retailer	0	5	0	1	4	1	0	0	4	3	1	1	20
Designated Representatives	74	410	142	162	50	243	315	263	177	156	80	188	2260

^{*}Calstars reports not available

Board of Pharmacy Licensing Statistics Three Year Comparison

License Counts	:		
Licensees	Jul-06	Jul-07	Jun-08
Clinic	1,029	1,083	1,151
Designated Rep	2,987	2,502	2,827
Hospital Pharmacy	584	583	580
Hypo Needle & Syringe	289	306	304
Intern	4,101	4,261	4,591
Licensed Sterile Injectable	254	262	278
Nonresident Pharmacy	297	318	345
Nonresident Wholesaler	418	482	528
Pharmacy	6,460	5,968	6,067
Pharmacist	33,928	.35,096	36,077
Pharmacy Technician	48,446	51,613	54,790
Vet Food-Animal Drug	19	20	23
Vet DR	57	57	60
Wholesalers	455	477	489
Total	99,324	103,028	108,110

Applications Received		24 + 4	
License Type	FY 05-06	FY 06-07	FY 07-08
Clinic	67	60	99
Designated Rep	634	384	448
Hospital Pharmacy	13	25	25
Hypo Needle & Syringe	16	14	. 13
Intern	1,510	1,614	1,818
Licensed Sterile Injectable	62	52	74
Nonresident Pharmacy	62	72	75
Nonresident Wholesaler	126	106	103
Pharmacy	936	423	436
Pharmacist	1,271	1,363	1,417
Pharmacist Exam	1,766	1,999	2,037
Pharmacy Technician	6,667	6,810	7,609
Vet Food-Animal Drug	. 3	1	. 2
Vet DR	4	12	16
Wholesalers	83	64	51.
Tota	1 13,220	12,999	14,223

Board of Pharmacy Licensing Statistics Three Year Comparison

Licenses Issued		·	
License Type	FY 05-06	FY 06-07	FY 07-08
Clinic	. 73	79	106
Designated Rep	599	367	407
Hospital Pharmacy	28	. 18	34
Hypo Needle & Syringe	10	20	8
Intern	1,411	1,510	1,654
Licensed Sterile Injectable	43	54	76
Nonresident Pharmacy	41	38	59
Nonresident Wholesaler	83	82	97
Pharmacy	964	463	427
Pharmacist	1,274	1,341	1,386
Pharmacy Technician	5,862	6,668	7,118
Vet Food-Animal Drug	0	3	1
Vet DR	5	6	10
Wholesalers	66	53	59
Tota	I 10,459	10,702	11,442

Licenses Renewed			
License Type	FY-05-06-	FY 06-07	FY 07-08
Clinic	900	961	944
Designated Rep	1,731	1,965	2,213
Hospital Pharmacy	545	547	485
Hypo Needle & Syringe	249	263	266
Licensed Sterile Injectable	126	233	224
Nonresident Pharmacy	198	219	249
Nonresident Wholesaler	253	265	404
Pharmacy	5,494	5,719	6,104
Pharmacist	15,130	14,897	16,933
Pharmacy Technician	18,653	21,197	23,195
Vet Food-Animal Drug	13	3	20
Vet DR	51	48	47
Wholesalers	331	382	455
Tota	ıl 43,674	46,699	51,539

Attachment 9

Fourth Quarterly Report on Committee Goals for 2007-08

LICENSING COMMITTEE

Goal 2:

Ensure the qualifications of licensees.

Outcome: Qualified licensees

Objective 2.1	Issue licenses within 3 working days of a completed application by June 30, 2011.
Measure:	Percentage of licenses issued within 3 work days.
T 1	1 Design 100 ground of all applications within 7 work days of vessint

Tasks:

Review 100 percent of all applications within 7 work days of receipt.

	Apps. Received:				Average Days to Process:				
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	
Pharmacist (exam applications)	392	268	307	1070	15	15	12	14	
Pharmacist (initial licensing)	608	363	221	225	10	5	2	2	
Pharmacy Intern	655	558	346	259	30	15	19	11	
Pharmacy Technician	1828	1681	1874	2226	16	20	10	18	
Pharmacies	127	124	66	68	18	23	30	15	
Non-Resident Pharmacy	20	19	16	20	17	23	13	17	
Wholesaler	12	11	11	17	20	27	14	10	
Veterinary Drug Retailers	0	2	0	0	10	39	0	0	
Designated Representative	111	94	127	132	10	15	15	14	
Out-of-state distributors	25	35	14	29	20	34	14	10	
Clinics	26	20	26	27	21	31	43	10	
Hypodermic Needle & Syringe Distributors	4	0	1	8	10	38	14	15	
Sterile Compounding	25	11	18	20	10	10	10	15	

Process 100 percent of all deficiency documents within 5 work days of receipt. 2.

	Average	Days to p	rocess def	iciency:
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	15	15	7	5
Pharmacist (initial licensing)	7	7	7	5
Pharmacy Intern	15	15	8	8
Pharmacy Technician	15	15	7	8
Pharmacies	4	15	7	14
Non-Resident Pharmacy	10	20	21	14
Wholesaler	10	18	14	14
Veterinary Drug Retailers	2	15	10	0
Designated Representative	5	15	7	5
Out-of-state distributors	10	18	14	14
Clinics	1	15	14	8
Hypodermic Needle & Syringe	2	15	10	3

3. Make a licensing decision within 3 work days after all deficiencies are corrected.

	Aver	Average Days to Determine to Deny/Issue License:							
	Qtr 1	Qtr 2	Qtr 3	Qtr 4					
Pharmacist (exam applications)	1	1	1	1					
Pharmacist (initial licensing)	1	1	1	1					
Pharmacy Intern	1	1	1	1					
Pharmacy Technician	3	5	5	5					
Pharmacies	4	4	7	5					
Non-Resident Pharmacy	5	5	8	4					
Wholesaler	4	5	3	5					
Veterinary Drug Retailers	1	1	1	1					
Designated Representative	1	3	2	3					
Out-of-state distributors	4	. 5	3	5					
Clinics	1	2	3	4					
Hypodermic Needle & Syringe	1	1	1	1					

4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.

		Licenses	s Issued:	
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist	612	358	220	196
Pharmacy Intern	637	580	213	224
Pharmacy Technician	1580	1759	2097	1682
Pharmacies	123	91	158	89
Non-Resident Pharmacy	15	17	14	13
Wholesaler	17	11	21	10
Veterinary Drug Retailers	0	1	0	0
Designated Representative	103	103	101	110
Out-of-state distributors	21	19	30	27
Clinics	22	15	51	18
Hypodermic Needle & Syringe	2	4	0	2
Sterile Compounding	14	6	49	7

5. Withdrawn licenses to applicants not meeting board requirements.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	1	0	0	0
Pharmacies	4	9	1	0
Non-Resident Pharmacy	1	0	0	0
Clinics	0	10	0	0
Sterile Compounding	0	0	0	0
Designated Representative	0	0	1	0
Hypodermic Needle & Syringe	0	1	0	0
Out-of-state distributors	1	21	4	0
Wholesaler	2	3	1	0

- 6. Deny applications to those who do not meet California standards.
- 7. Responding to email status requests and inquiries to designated email addresses.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	1,863	1199	1503	1512
Pharmacy Technicians	1,092	1112	1059	1136
Site licenses (pharmacy, clinics)	1,156	1047	928	1080
Site licenses (wholesalers, nonresident pharmacies)	1,103	1097	859	1192

8. Responding to telephone status request and inquiries.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	671	84	112	196
Pharmacy Technicians	150	70	123	126
Site licenses (pharmacy, clinics)	243	252	195	134
Site licenses (wholesalers,	370	230	211	296
nonresident pharmacies)				

Objective 2.2	Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2011.					
Measure:	Percentage of cash	Percentage of cashiered application and renewal fees within 2 working days.				
Tasks:	1. Cashier appli					
	1st Qtr 06/07:	The average processing time for processing new application fees is 2-3 working days.				
	2nd Qtr 06/07	The average processing time for processing new application fees is 2-3 working days.				
	3rd Qtr 06/07	The average processing time for processing new application fees is 3 working days.				
	4th Qtr 06/07					
	1st Qtr 07/08:	The average processing time for processing new application fees is 2-3 working days.				
	2nd Qtr 07/08	The average processing time for processing new application fees is 2-3 working days.				
	3rd Qtr 07/08					
	4th Qtr 07/08	: The average processing time for processing new application fees is 2-3 working days.				
	2. Cashier renev	val fees.				
·	1st Qtr 06/07:	The average processing time for cashiering is 2-3 working days.				
	2nd Qtr 06/07	: The average processing time for cashiering is 2-3 working days.				
	3rd Qtr 06/07	: The average processing time for cashiering is 2-3 working days.				
	4th Qtr 06/07	: The average processing time for cashiering is 2-3 working days.				
	1st Qtr 07/08:	The average processing time for cashiering is 2-3 working days.				
	2nd Qtr 07/08	3: The average processing time for cashiering is 2-3 working days.				
	3rd Qtr 07/08	: The average processing time for cashiering is 2-3 working days.				
	4th Qtr 07/08	: The average processing time for cashiering is 2-3 working days.				
	Secure online	e renewal of licenses.				
	1st Qtr 06/07:					
		programs to convert to DCA Applicant Tracking Program.				
	Jan. 2007:	Board converts all application programs to DCA's Applicant Tracking				
n 107 - No. / Agujuja C. V. Arti		Program. See Objective 2.4, Task 7 below.				

Objective 2.3	Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2011.			
Measure:	Percentage of licensing records changes within 5 working days.			
Tasks:	1. Make address and name changes.			
	1st Qtr 06/07: Processed 1,832 address changes.			
	2nd Qtr 06/07: Processed 1,322 address changes.			
	3rd Qtr 06/07: Processed 1,613 address changes.			
	4th Qtr 06/07: Processed 1,857 address changes.			
	1st Qtr 07/08: Processed 1,990 address changes.			
	2nd Qtr 07/08: Processed 1,470 address changes.			
	3rd Qtr 07/08: Processed 1,528 address changes.			
	4th Qtr 07/08: Processed 1,827 address changes.			
	Process discontinuance of businesses forms and related components.			
	1st Qtr 06/07: Processed 41 discontinuance-of-business forms. Processing time is 46 days.			
	2nd Qtr 06/07: Processed 0 discontinuance-of-business forms.			
	3rd Qtr 06/07: Processed 72 discontinuance-of-business forms. Processing time is 30 days.			
	4th Qtr 06/07: Processed 38 discontinuance-of-business forms. Processing time is 30 days.			
	1st Qtr 07/08: Processed 69 discontinuance-of-business forms. Processing time is 30 days.			
	2nd Qtr 07/08: Processed 64 discontinuance-of-business forms. Processing time is 30 days.			
	3rd Qtr 07/08: Processed 0 discontinuance-of-business forms.			
	4th Qtr 07/08: Processed 183 discontinuance-of-business forms. Processing time is 30 days.			
	3. Process changes in pharmacist-in-charge and designated representative-in-charge.			
	1st Qtr 06/07: Processed 247 pharmacist-in-charge changes. Average processing time is			
	30 days. Processed 0 designated representative-in-charge changes.			
	2nd Qtr 06/07: Processed 382 pharmacist-in-charge changes. Average processing time is			
	30 days. Processed 5 designated representative-in-charge changes. Average			
	processing time is 10 days.			
	3rd Qtr 06/07: Processed 358 pharmacist-in-charge changes. Average processing time is			
	30 days. Processed 0 designated representative-in-charge changes.			
	4th Qtr 06/07: Processed 544 pharmacist-in-charge changes. Average processing time is			
	30 days. Processed 14 designated representative-in-charge changes. Average			
	processing time is 14 days.			
	1st Qtr 07/08: Processed 368 pharmacist-in-charge changes. Average processing time is			
	30 days. Processed 30 designated representative-in-charge changes. Average			
	processing time is 30 days.			
	2nd Qtr 07/08: Processed 315 pharmacist-in-charge changes. Average processing time is			
	30 days. Processed 31 designated representative-in-charge changes. Average			
	processing time is 30 days.			
	3rd Qtr 07/08: Processed 372 pharmacist-in-charge changes. Average processing time is			
	15 days. Processed 17 designated representative-in-charge changes. Average			
	processing time is 30 days.			
	4th Qtr 07/08: Processed 422 pharmacist-in-charge changes. Average processing time is			
	23 days. Processed 3 designated representative-in-charge changes. Average			
	processing time is 15 days.			
	4. Process off-site storage applications.			
	1st Qtr 06/07: Processed and approved 42 off-site storage applications. Average processing			
	time is 30 days.			
	1st Qtr 07/08: Processed and approved 42 off-site storage applications. Average processing			
	time is 30 days.			

5.	Transfer	of intern	hours to	other states.	
J.	I I U I I J I C I	O1 1111C-111	110013 10	Othici States.	

1st Qtr 06/07: Processed 76 applications. Average processing time is 30 days.
2nd Qtr 06/07: Processed 45 applications. Average processing time is 30 days.
1st Qtr 07/08: Processed 76 applications. Average processing time is 30 days.
2nd Qtr 07/08: Processed 37 applications. Average processing time is 30 days.
3rd Qtr 07/08: Processed 17 applications. Average processing time is 30 days.
4th Qtr 07/08: Processed 53 applications. Average processing time is 20 days.

Objective 2.4	lmp	Implement at least 25 changes to improve licensing decisions by June 30, 2011.			
Measure:	Nur	Number of implemented changes.			
Tasks:	1.		In y 26 states do not allow the use of a CA license as the basis for transfer license to that state. Survey of some states indicate misunderstanding of why California cannot accept NAPLEX scores earned before January 1, 2004. Educational efforts, on a state by state basis, initiated.		
		March 2007: May 2007:	Pennsylvania agrees to accept California NAPLEX scores. At National Association of Boards of Pharmacy meeting several states agree to reconsider their position against accepting California scores.		
	2.	Evaluate the o	drug distribution system of clinics and their appropriate licensure.		
	3.		Department of Corrections on the licensure of pharmacies in prisons. Meet with the Department of Corrections Receiver to discuss possible regulatory structures for drug dispensing and distribution within correctional facilities.		
·	4.	pandemic and	al and state officials on emergency preparedness and planning for disasters. Planning to include the storage and distribution of drugs to taccess and safety. Committee hears presentation by DHS on emergency preparedness. Presentation by Orange County and LA emergency response staff at NABP District 7 & 8 meeting. Board meeting has presentation by DHS and board develops policy statement for licensees in responding to declared emergencies.		
		Jan. 2007:	Board publishes disaster response policy statement.		
		Feb. & March 2			
		April - June 20	07: Board continues to participate in SURGE planning activities and in a joint public/private partnership project envisioned by the Governor.		
		June 2007:	Board staff aids in contract evaluation to select a consultant to provide pre- emergency registration of health care providers.		
		Sept. 2007: Oct. 2007:	Board attends Rough & Ready Demonstration in Orange County. Board considers legislative proposal to license mobile pharmacies for deployment during declared disasters.		
			Staff resume attendance at ESAR VHPs meeting of EMSA. Board activates disaster response policy to allow rapid response to patients affected by California wild fires. Use of subscriber alerts proves effective in conveying board messages to licensees in effected areas.		
		Dec. 2007:	Committee hears presentations on emergency preparedness by California Department of Public Health, L.A. County and Orange County emergency response offices. Focus continues on getting pharmacists prescreened and registered for		
			disaster response. Discussion also includes lessons learned during California wild fires, ESAR-VHPS, renamed California medical volunteers, readied for widespread promotion by January 1, 2008 by EMSA.		
	5.	Evaluate the r	need to issue a provisional license to pharmacy technician trainees.		

6. Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians.

Sept. 2006: Committee hears presentation on ExCPT exam approved for certification of

technicians by five states. Committee directs staff to evaluate exam for

possible use in California.

Dec. 2006: DCA recruiting for Chief of Examination Resources Office; review postponed.

Additional methods to accomplish review considered.

March 2007: DCA recruiting for Chief of Examination Resources Office; review postponed.

Additional methods to accomplish review considered.

May 2007: Board seeks private contractor to evaluate both ExCPT and PTCB exams for

job validity.

Sept. 2007: Board required to check with other state agencies to ensure that state-

employed PhD psychometricians are not able to perform this review before the board can contract for services. Committee recommends delay until CSHP and CPhA complete their review of pharmacy technician training and

knowledge.

Oct. 2007: Board postpones work on this topic until CSHP and CPhA complete their

review.

Apr. 2008: Future work on the training of technicians will occur as joint activities of the

pharmacist associations.

Legislation to require an exam and continuing education for pharmacy

technicians is dropped (AB 1947)

June 2008: Board participates in CSHP sponsored stake holder meeting

7. Implement the Department of Consumer Affairs Applicant Tracking System to facilitate implementation of I-Licensing system, allowing online renewal of licenses by 2008.

July 2006:

Board executive officer becomes executive sponsor of program.

Nov. 2006:

Board completes system identification of parameters for each licensing

program.

Dec. 2006-Jan. 2007: Preparatory work and pilots completed; Board Staff initiates transfer

to ATS system as sole platform for applicant tracking for all

licensing programs.

March 2007: Work on securing vendors for I-Licensing continues. Staff changes at DCA

may delay implementation.

June 2007: DCA hires additional staff for I-Licensing project. Implementation for board

programs delayed until mid-2009.

Aug. 2007: Executive Officer still on executive steering committee.

2nd Qtr. 07/08: Board staff designed to integrate board requirements into system, a major

undertaking of staff time.

Executive Officer continues on executive steering committee.

3rd Qtr. 07/08: Department works on securing vendors.

Board is up to date in performing implementation components.

8. Participate with California's Schools of Pharmacy in reviewing basic level experiences required of intern pharmacists, in accordance with new ACPE standards.

3rd Qtr 06/07: Board attends 3 day-long working sessions convened by California's schools

of pharmacy to develop list of skills students should possess by end of basic

intern level experience (about 300 hours).

Oct. 2007: Board considers basic internship competencies developed under the

program and develops letter of support.

9. Implement new test administration requirements for the CPJE.

March 2007: Board advised about new exam vendor for CPJE effective June 1, 2007. Board

notifies all CPJE eligible candidates of pending change, advises California

schools of pharmacy graduating students and applicants in general.

June 2007:

Shift to new exam vendor, PSI, takes place. New Candidates Guide is printed

and distributed. Some transition issues to new vendor exist and are being

worked on.

Oct. 2007:

Transition efforts to PSI continue.

2nd Qtr. 07/08: Transition efforts to PSI continue.

3rd Qtr. 07/08: New security procedures put in place and corresponding revisions to the

Candidates' Guide are published and released.

10. Participate in ACPE reviews of California Schools of Pharmacy.

Oct. 2007:

Board participates in review of California Northstate College of Pharmacy.

Jan. 2008:

Board participates in review of UCSF.

March 2008:

Board participates in review of Touro.